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TASK ASSIGNMENT FORM
Antimicrobial Division/Regulatory Management Branch I

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Type of Data:	Product								-
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Response Date:

Response Code:

TASK ASSIGNMENT FORM Antimicrobial Division/Regulatory Management Branch I

A	Compl	leted by Product	Manag	ger		
PRODUCT REVIEWER:	Tracy			RMB_1	TEA	M_3#
Description of Action:	odated muste	lopes			e Symbol/Reg N	
Decision No. 347493	Submission No. 76	5702	Fee fo	or Service Action	Code:	
FQFA Action Code: 302	Non-FQPA Action	Code:	F	ee for Service Fo	ee: \$	
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APPLICATION DATE	8	3			2004	
PA PIN DATE	8	6			2004	
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В	For A	rctic Slope Contr	act On	ily		
Contractor: Arctic Slope		Contract No.: 03	32	ARCTIC	SLOPE/MANAC	GER
Draft Task: Signature (Est. hrs)	<u>v</u>	Final Task: Sign (Total hrs		0		
C Reviewer's Comments:						
		16			Ser o 9 2004	

Response Date:

Response Code:

Mr. Timothy C. Moses
President, Antimicrobials & Biocides Division
Nova BioGenetics, Inc.
8601 Dunwoody Pl., Suite 338
Atlanta, GA 30350

OCT 28 2004

SUBJECT:

BioShield AM500 I

EPA Registration Number: 75497-2 Application Dated: August 3, 2004 Receipt Date: August 6, 2004

Dear Mr. Timothy C. Moses:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is unacceptable for the reasons listed below.

- Revisions to Master Label
- Collateral and Master Label combined into one document

Deficiencies

Addition of Surfaces/Sites to Label

Your application states that you have made changes to your label such that it is in agreement with a similar product: 64881-3, Aegis Antimicrobial. Although a number of the proposed changes are similar to approved sites on the cited Aegis label, the following would be considered new uses as they are not on the cited label:

Acrylics
Airplanes interior (non food contact)
Airplane recirculating and air handling systems including duct work
Pool filters (i.e. filtration system non-woven)

Dyc stuff for fabrics

CONCURRENCES

SYMBOL 75/0C

BURNAME 75/0C

DATE 10/28/04

EPA Form 1320-1A (1/90)

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Exterior concrete, painted and unpainted (such as decks and ceilings, driveways, sidewalks)

Evaporative coils

Gel Coats

Formica

HVAC Metal Duct Work

Insulation

Latex and latex emulsions

Metal and wood framing studs

Particle Board

Patio and Pool-side furniture

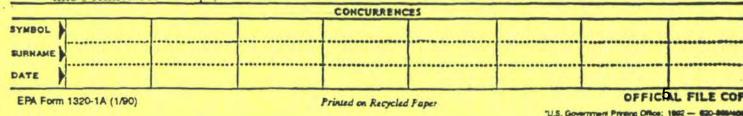
Vinyl exterior decking and siding

Wood framing (i.e. sill plates and window casing, studs, rafters, joists, beams, headers, plywood, trim), exterior decks

If you are unable to cite another label of a formulation which contains the same active ingredient and is similar or identical to your product, then the addition of these cites to your label would be classified as new uses for this active ingredient, would be subject to the Pesticide Registration Improvement Act (PRIA) with a fee of \$10,000 (indoor non-food) to \$25,000 (outdoor wood and other uses) depending on the requested new use and would require a risk assessment, citation of data to support such an assessment and possibly additional data submitted as well as specific language on your labeling which clearly identifies what is to be treated.

Specifically, the following surfaces require clarification: acrylics (what made of acrylic?) Airplane interiors (what part(s) will be treated?), dye stuff for fabrics (what items made of fabric and what types of fabrics will be treated?), gel coats (to what are these applied?), insulation (for which applications? what is the insulation made of?), latex and latex emulsions (to what are these applied?). Several of these sites, in addition to requiring a risk assessment would also require very specific directions for use such as Airplane recirculating and air handling systems including duct work and HVAC metal duct work. If you intend to treat the metal that will be used to fabricate duct work at the point of manufacture, refer to the label for 71227-1. Although this product contains a different active ingredient, the directions for use would serve as a good model of the language which would likely be required on your label. If you intend for your product to be applied to an in place HVAC system a separate risk assessment is required, data compensation and additional data may be needed depending on the data which is in house. Refer to the labeling of 67212-1 as a model of the directions which would be required on the labeling for such a use.

Although this active ingredient is approved as a spray to an in place Formica surface, likely a countertop, the Agency has very different concerns should this product be incorporated into a Formica countertop at the point of manufacture. This type of use would require an indirect food additive clearance since Formica could be used in a commercial establishment where residues are regulated by the FDA as indirect food additives. Should this product be incorporated into Formica countertops, there could be indirect transfer of the residue to a processed food item.



The use of this active ingredient on certain exterior surfaces including decks would require specific data be submitted or cited for the associated risk assessment. The following Human Exposure Data, Application is required: Product Use Information 875.1700 (description of how the product is used), Dermal Exposure 875.1100, 875.1200, 875.1600 (the American Chemistry Council (ACC) Biocides Panel Task Force is currently working on this, you might inquire about using this data), Inhalation Exposure Outdoor 875.1300, 875.1600. The following Human Exposure Data, Post-Application is required: Product Use Information 875.2700, Description of Human Activity 875.2800 (who will be using the area and how will they be using it), Surface Residue Dissipation/Dislodgeable Residue (Surface Wipe Sampling) 875.2300, 875.2900.

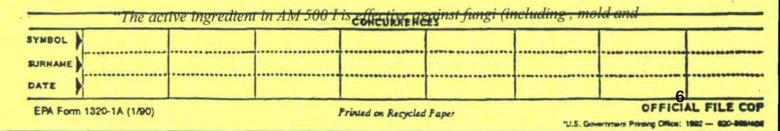
In addition, identification of the following surfaces must be revised as the cited label 64881-3 is for treatment of <u>interior</u> surfaces only. Add the qualifier "interior" to the following: Ceilings (such as gypsum, plaster); Concrete mixture added directly during concrete preparation; flooring (such as wood, linoleum, ceramic and vinyl tile); hard surfaces such as glass fixtures, stainless steel, fiberglass, marble, porcelain, chrome, aluminum, furniture; and Interior concrete ceilings and floors (excluding food contact areas).

Revise your label to specify the items/surfaces made of the following material on which you anticipate this product may be used: hard surfaces such as glass fixtures, stainless steel, fiberglass, marble, porcelain, chrome, and aluminum (i.e. what items made of aluminum?)

You are also reminded that the labeling of the products used as your source(s) of active ingredient must either be in agreement with your labeling or data compensation and risk assessments when warranted will be required to add any additional uses. Compare your labeling to that of your source(s) products.

Label Comments

- 1. Revise your Environmental Hazards statement to be in agreement with the cited label as follows: "...This may be accomplished by the use of sandbags to confine..." Add the following statement to this section: "Floor drains in areas of material use should be protected with absorbent material or barrier material to contain accidental spills."
- 2. The chemical structure on the proposed labeling is incorrect. The Nitrogen may accept four bonds not the Hydrogen atom. Revise the structure diagram to agree with the last accepted collateral label for this product.
- 3. Add the following statement to your label: "Do not use in any application involving direct or indirect food or drinking water contact."
- 4. As per the Agency letter of 3/3/2004, add the following two statements directly below the heading "Approved Uses" on page three:



mildew) and algae as a static agent."

"AM 500 I can be used for incorporation into and treatment of the following items or substrates to impart bacteriostatic/fungistatic activity:"

- 5. Add the following statement to your label: "This product is registered as a microbiostatic agent for materials preservation only; neither this product nor the articles treated with this product may state or imply any public health claims. Articles or surfaces treated with this product will be exempt from FIFRA regulation pursuant to 40 CFR 152.25 (a) if the intended use for incorporating this material into a treated article or substance is for the protection of the article or substance itself."
- 6. Your application for pesticide indicates that this product is only marketed in metal containers. If this is the case revise the "Container Disposal" statement by deleting: "by burning, If burned, stay out of smoke." If this is not the case, revise your application for pesticide to include all container types and revise the "Container Disposal" statement accordingly, referring to PR Notice 83-3 for guidance.

General Comments

Due to the numerous concerns identified above, we are unable to perform a complete label review at this time. We suggest you meet with us prior to resubmitting this application for further clarification on any of these issues. Submit revised labeling including specific directions for use and clarifiers as identified above, product specific and generic data matrixes as well as data compensation forms. Depending on the uses you intend to pursue, additional data may be required at resubmission.

Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely.

Velma Noble

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510C)

7510C:T.Lantz:10/25/04:75497-2b

EPA Form 1320-1A (1/90)

Printed on Recycled Faper

Receipt for Sec	tion 3
Regulatory Type:	Product Registration - Section 3 Resubmission: O Yes O No Amendment Fee For Service: O Yes O No
Company:	75497 NOVA BIOGENETICS, INC:
Risk Manager:	Antimicrobials Division, Risk Management Team 31
Product #: Override#:	75497-2 Product Name: BIOSHIELD AM 500 I
Me Too Section3:	Me Too Product Name:
Application De	
Fast Track:	New Ingredient:
Receipt Desc	
Form A:	New Ingredient Request Date: New Ingredient Received Date: Signature Date: Signature Date:
TOTAL A.	Signature Date



BIOSHIELD® AM 5001 ANTIMICROBIAL AGENT

(For Manufacturing Use Only).

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Octadecylaminodimethyltrihydroxysilyl propyl ammonium chloride.....

KEEP OUT OF REACH OF CHILDREN

WARNING

EPA EST. xxxxx-GA-xxxx

95.0%

NET CONTENTS: 2, 4, 8, 16, 20, 22, or 36 fluid oz.; 1, 5, 55, or 275 gal

EPA Reg. No. 75497-2

Have the product container or label with you when calling the poison control center or doctor, or going for treatment. FIRST AID

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call poison control center or doctor for treatment advice.

IF INHALED:

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.
 - Call a poison control center or doctor for further treatment advice.

IF ON SKIN:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
 - Call a poison control center or doctor for treatment advice.

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

 A antimicrobial agent is an agent that inhibits the growth of odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae. This product does not protect users or others against food-borne or disease-causing bacteria.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

clothing. Avoid contact with skin and avoid breathing vapor. Wear protective eyewear (goggles or face shield). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

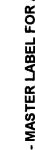
This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional

equivalent to that of AM 500l or with the addition of Triton X-100 nonionic detergent at a final concentration of 10,000 ppm (1.0 percent De-activation of AM 500I can be achieved by the addition of anionic surfactant (such as soap, sulfonates, sulfates) in quantity volume/volume) or greater to bath solutions up to 1.0 percent volume/volume of AM 500l.

floor drains and sandbags to confine the spill to facilitate cleanup and disposal. Contaminated sand may then be disposed of by burial Every effort should be made to contain accidental spills of AM 500l to the immediate area. This may be accomplished by the use of in an approved landfill. Many spills may be cleaned up with rags by wiping and/or moping and allowing the liquid to absorb into the fabric. The rags may then be disposed of by incineration.

TYPICAL PROPERTIES

/alues are not intended for use in preparing specifications :اجاء			%0.5		Miscible in all	Stable to 230C	Silicone quaternary ammonium salt		Surface bond ability	BioGenetics for information regarding specifications
These values are CH ₃	Structure[(CH ₃ O) ₃ Si(CH ₂) ₃ N-C ₁₈ H ₃₇]+Cl	_ - S	Concentration	Appearance	Solubility	Proportions with water, ethanol, and methanol thermal stability	Туре	Physical Form	Special Properties	



Primary Uses: As an active ingredient for formulating microbiostats for use in laundry additives, carpet treatment products, upholstery and drapery treatment products to give a Bacteriostatic, fungistatic, mildewstatic activity,

BENEFITS

The following benefits are derived when a formulation containing the active ingredient is applied to a surface:

- · Provides freshness and combats deterioration caused by bacteria, fungi, and algae.
- Inhibits growth of bacteria and mildew on the treated article.
- Prolongs the life of an article by inhibiting the growth of bacteria and mildew.
- Resists development of bacterial and fungal odors.
- Retains freshness by resisting the growth of odor-causing bacteria and imparts odor resistance.
- Product performance with little degradation up to 375°F.
- Durability -NOVA BIOGENETICS AM 500l imparts biostatic activity to the surface of a wide variety of substrates.
- Increased efficiency-through proper application, durable bacteriostatic, fungi static and algaestatic surfaces can be attained with a minimum amount of AM 5001

Materials treated with formulations containing the microbiostatic agent AM 500I are preserved by the bacteriostatic, fungistatic and algaestatic action imparted by the active ingredient. AM500l inhibit the growth of microorganisms that are responsible for causing odor, discoloration, and deterioration. It also provides residual inhibition of microorganisms to aid in the control of these deleterious effects. AM 500l forms a coating on a wide variety of substrates and microbiostatic action is exhibited on contact.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

AM 500I may be used in materials that are incorporated into manufactured products listed on this label. The final article may contain from 0.1 For use in Formulating, Manufacturing, and Fabricating of Treated Article Products Specified under "approved uses." to 1.0% by weight active ingredient.

APPROVED USES

treatment products. AM 500I can be used for incorporation into and treatment of the following items to impart bacteriostatic/fungistatic (mold AM 500I is approved for use in formulating microbiostats for use in laundry additives, carpet treatment products, upholstery and drapery and mildew) activity

- Acrylics
- Air filters for furnaces, air-conditioners, air purification devices, automobiles, recirculating air handling systems
 - Airplanes interior (non food contact)
- Airplane recirculating and air handling systems including duct
- Air filters/materials
- Aquarium and pool filter material (i.e. filtration system nonwovens)
- Bed sheets, blankets, and bedspreads
 - Buffer pads (abrasive and polishing)
- Carpets and draperies
- Ceilings (such as gypsum, plaster)
 - Cellulose sponges
- Concrete admixture added directly during concrete preparation (not to be used in treatment of storm drains)
- Concrete additive for sewer pipes, manholes and concrete sewer structures (not to be used in treatment of storm drains)
- manholes and concrete sewer structures (not to be used in Concrete additive for repair and renewal of sewer pipes, treatment of storm drains)
- Dye stuff for fabrics
- Exterior concrete, painted and unpainted (such as decks and ceilings, driveways, sidewalks)
- Exterior walls (such as stone, concrete, brick, wood, stucco, driver, plaster)
 - Evaporator coils
- Fiberfill for upholstery, sleeping bags, apparel, where the fiber is cotton, natural down, nylon, polyester, rayon, or wool
 - Fiberglass duct board
- Fire hose fabric
- Flooring (such as wood, linoleum, ceramic, and vinyl tile)
- Gel coats
- Hard surfaces such as Formica, glass fixtures, stainless steel fiberglass, marble, porcelain, chrome, aluminum, furniture.
- Humidifier belts
- HVAC metal duct work
- Insulation
- and drywall; painted and non-painted) (excluding food contact Interior walls (such as wood, concrete, plaster concrete block,

- Interior and exterior concrete ceilings and floors (excluding food contact areas)
- Latex and latex emulsions
- Mattress pads and ticking
- Men's underwear and outerwear
- Metal and wood framing studs
- Non-woven disposable diapers
- Non-woven polyester
- Outerwear apparel (jackets, sweaters, sweatshirts, coats, raincoats, overcoats, jerseys, ponchos)
- textile coatings, extrusion coatings, architectural coatings and maintenance coatings, films, laminates and finishes including cement, epoxy laminating resins, and blends and copolymers preservative for protection of paint and coating film. Types of paints and coatings include: latex indoor/outdoor paints and alkyd, urethane, enamel, epoxy, siloxaline, amino resins, coatings, amino resins, resins used as additive mixes for aliphatic coatings, vinyl ester and polyester coatings, gel Paints and coatings: AM 500I can be used as an in-can overlays, anti-corrosion coatings, fire-resistant coatings, stains, wood stains, architectural paints, lacquer and thereof
- Particle board
- Patio and pool-side furniture
- Polyurethane and cellulose foam for household, industrial, and institutional sponges and mops
 - Polyurethane and polyethylene foam, when covered
- Polyurethane foam for packaging and cushioning in non-food contact applications
 - Polyurethane foam used as a growth medium for non-food crops and plants
- Pre-moistened towelettes and tissue wipes (these do not impart pesticidal properties)
 - Roofing materials defined as shingles, roofing granules, wood shakes, felt, stone and synthetic overcoats
 - Sand bags, tents, tarpaulins, sails, and ropes
 - Shoes (athletic and casual)
 - Shoe insoles
- Shower curtains

- Socks comprised of nylon, nylon/orlon, cotton/nylon, linen/Lycra, acrylic/polypropylene/nylon/Lycra, wool/silk/nylon/Lycra and wool/acrylic/nylon/Lycra
- Throw rugs
- Toweling made of 100 percent cotton, 100 percent polyester, and blends of the two fibers
- Toilet tank and seat covers
- Umbrellas
- Upholstery made of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polyolefin, polypropylene, rayon, spandex, vinyl, wool

- Vacuum cleaner bags and filters
- Vinyl exterior decking and siding
- Vinyl paper-wallpaper for non-food contact surfaces
- Disposable wiping cloths that can be used for multiple purposes such as dusting or washing furniture, cars, walls, windows, floors, appliances, dishes, counter tops; the wiping cloths do not impart pesticide properties
 - Wood framing (i.e. sill plates and window casing, studs, rafters, joists, beams, headers, plywood, trim), floors, hardwood floors, fixtures, exterior decks
 - Women's hosiery and intimate apparel

EPA REGISTRATION REQUIREMENTS:

The applications for which this product is used may require approval by the Environmental Protection Agency on an end-use basis in regard to claims made thereof. Formulators are responsible for satisfying registration requirements for their products.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in original, tightly closed containers below 30°C (86°F) and above 0°C (32°F) in a secure area inaccessible to children and away from food or feed

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities, by burning. If burned, stay out of smoke. FOR MORE INFORMATION CONCERNING THIS PRODUCT, PLEASE CONSULT THE MATERIAL SAFETY DATA SHEET (MSDS). THE MSDS CAN BE OBTAINED BY WRITING Nova BioGenetics Inc. 8601 Dunwoody Place, Suite 338, Atlanta, Georgia 30350 or obtained from our website: www.novabiogenetics.com.

IMPORTANT: WARRANTY AND DISCLAIMER INFORMATION

Contrary to bulletin instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to the seller, and buyer assumes the risk of any Nova BioGenetics Inc., warrants that the product conforms to its chemical description and is reasonably fit for the purposes stated in this bulletin when used in accordance with directions under normal conditions of use; but this warranty of fitness for a particular purpose does not extend to the use of this product

Nova SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING THE WARRANTY OF MERCHANTABILITY. such use.

Norm Cook/DC/USEPA/US 10/26/2004 06:10 PM

To Tracy Lantz/DC/USEPA/US@EPA

Nader Elkassabany/DC/USEPA/US@EPA, Norm

Cook/DC/USEPA/US@EPA

bcc

Subject Re: Data required for quat on outdoor wood use

Hi Tracy

Based upon what you showed me, here're the data rqmts....Norm



Note to Tracy on proposed use pattern. Oct. 2004. wpd

Tracy Lantz/DC/USEPA/US



Tracy Lantz/DC/USEPA/US 10/26/2004 03:49 PM

To Norm Cook/DC/USEPA/US@EPA

СС

Subject Data required for quat on outdoor wood use

Please don't forget to send me the data requirement info.

Thanks for your assistance.

Human Exposure (Application and Post-Application)

Human Exposure Data Requirements (Application

nan Exposure Data Requiremen		P'
Data Requirements/Guideline Number	Test Substance	Proposed Use Pattern (Treatment of Decks Including Fogging)
Product Use Information 875.1700	ТЕР	R
Dermal Exposure 875.1100 875.1200 875.1600 RC Ploid Park	TEP	R
Inhalation Exposure Outdoor 875.1300 875.1600	ТЕР	R
Biological Monitoring 875.1500 875.1600	TEP	CR (conditionally

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Human Exposure Data Requirements Post-application

Human Exposure Data Requiremen	165 7 1 OSC-applica	
Data Requirements	Test Substance	Proposed Use Pattern (Treatment of Decks Including Fogging)
Product Use Information 875.2700	TEP	R
Description of Human Activity 875.2800 On dean	ТЕР	R
Surface Residue Dissipation/Dislodgeable residue (Surface Wipe Sampling) 875.2300 875.2900 [Also, refer to CPSC (2003a), CPSC (2003b), CPSC (2003c), CPSC (2003d), CPSC (2003e), RTI International (2003)]	ТЕР	R
Dermal Exposure 875.2400 875.2900	TEP	€ R
Inhalation Exposure 875.2500 875.2900	ТЕР	€ R

Data Requirements	Test Substance	Proposed Use Pattern (Treatment of Decks Including Fogging)
Biological Monitoring 875.2600 875.2900	ТЕР	CR

References

Consumer Product Safety Commission (CPSC). (2003a). Briefing Package. Petition to Ban Chromated Copper Arsenate (CCA)-Treated Wood in Playground Equipment. (Petition HP 01-3). February 2003.

Consumer Product Safety Commission (CPSC). (2003b). Briefing Package. Staff Recommendation to Ban Use of Chromated Copper Arsenate (CCA)-Treated Wood in Playground Equipment. (Petition HP 01-3). October 2003.

Consumer Product Safety Commission (CPSC). (2003c). Memorandum dated January 13, 2003, from Mark S. Levinson to Patricia Bittner, "Statistical Analysis of CCA-Treated Wood Study Phase III".

Consumer Product Safety Commission (CPSC). (2003d). Chromated Copper Arsenate (CCA) Pressure Treated Wood Analysis Exploratory Studies Phase I and Laboratory Studies Phase II. Memorandum from David Cobb, Chemist, to Patricia Bittner, Project Manager, January 2003.

Consumer Product Safety Commission (CPSC). (2003e). CCA-Treated Wood Field Study Phases III and IV. Memorandum from David Cobb, Chemist, and Dwayne Davis, Chemist, to Patricia Bittner, Project Manager, January 2003.

RTI International. 2003. Assessment of Exposure to Metals in CCA-Preserved Wood: Full Study. Prepared for the American Chemistry Council.

64881-3

11/19/2003

page 176

NOV 19 2003

Mr. Harvey Steinberg AEGIS Environmental Management Inc. 3106 Swede Avenue Midland, MI 48648-3483 This is then too of the stage of the too y

Subject:

AegisAntimicrobial

EPA Registration No. 64881-3 Amendment Date: August 20, 2003 EPA Receipt Date: August 21, 2003 formulation is not similar

Dear Mr. Steinberg,

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable with the following conditions:

Update First Aid Statements per PR Notice 2001-1

Conditions

Revise the label as follows:

- Based on the "Precautionary Statements," this product contains 50% methanol. Revise
 the phrase, "contains over 49% methanol," under the ingredient's statement to be
 consistent with the amount of methanol cited in the "Precautionary Statements."
- Make the following "Precautionary Statement" revisions:
 - a) Delete "Concentrate" from the statement "Concentrate causes irreversible eye damage and skin irritation." Precautionary labeling is based on the acute toxicity data submitted on the chemical in the containers that are sold. Based on the submitted data, this product is toxicity category I for primary eye irritation. If you feel this product's toxicity is reduced in use dilution, you may submit use dilution data as prescribed in the Label Manual 3rd edition, chapter 7 for use dilution precautionary labeling.
 - b) This product is categorized as toxicity II for acute inhalation. The statement, "may be fatal if inhaled, must appear after "skin irritation." The label must be specific in stating how "appropriate measures must be taken" by specifying what type of respirator must be utilized when handling this product. Based on previous discussions, you stated that the

"Dust mist filtering respirator" as suggested in the Agency letter dated May 22, 2003 was not appropriate for this type of product. In the absence of an alternative, you must state "Wear a NIOSH approved respirator with any N, R, P, or HE filter."

If this is not in agreement with the practices at your facilities, submit a notification adding the appropriate respirator information.

- c.) Revise the "wash thoroughly with soap and water after handling" statement to include the phrase, "..and before eating, drinking, or using tobacco."
- 2. Delete the statement, "AEGIS Antimicrobial can also be used to impart biostatic (bacteriostatic, fungistatic, algistatic) activity to substrates for the following applications" along with the box below it. You must submit a separate amendment to add the use sites from AEM 5700 label, 64881-1. Please note: many of the use sites listed for AEM 5700 are not appropriate for use by homeowners or commercial applicators.
- 3. On page 3: revise the first statement, "wear goggles or faceshield and rubber gloves when handling the concentrate" to state "wear goggles or faceshield, protective clothing, rubber gloves, and respirator." This text must agree with the "Precautionary Statements" on the front panel. As stated earlier, if you want alternative precautionary labeling based on the use dilution, you must submit data.
- 4. According to PR Notice 83-3 and Label Manual 3rd edition, any pesticide that is classified in toxicity category I or II for acute inhalation and/or I for primary eye irritation, the 1st statement under "Pesticide Disposal" must read "Pesticide is acutely hazardous."

General Comments

A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Jacqueline McFarlane at (703) 308-6416.

111/

Velma Noble

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510C)

. 56%

AEGIS™ Antimicrobial

A SILANE QUATERNARY AMMONIUM SALT

EPA Reg. lo. 64881-3

EPA Est. 34292-MI-01

ACTIVE IN GREDIENT: 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride .

INERT INGREDIENTS: .

CONTAINS OVER 49% METHANOL

KEEP OUT OF REACH OF CHILDREN

DANGER! & POISON

	FIRST AID
Have product contai	ner or label with you when calling Poison Control Center or doctor, or going for treatment.
If inhaled:	 Move person to fresh air. If person is not breathing, call 911or ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a Poison Control Center or doctor for treatment advice.
If in eyes	 Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after first 5minutes, then continue rinsing. Call a Poison Control Center or doctor for treatment advice.
If in skin or clothing:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a Poison Control Center or doctor for treatment advice.
if swallowed:	 Call a Poison Control Center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a Poison Control Center or doctor. Do not give anything by mouth to an unconscious person.

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS.

DANGERI CORROSIVE, CONTAINS 50% METHANOL, CONCENTRATE CAUSES

IRREVERSIBLE EYE DAMAGE AND SKIN IRRITATION. May be harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin, or on clothing. Wear protective eyewear, rubber gloves, and protective clothing. May be fatal if inhaled. Do not breathe vapor. Appropriate measures should be taken to prevent the accumulation of hazardous concentrations of methanol vapors in the work area. Wash

thorough with soap and water after handling. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS:

This pestic the is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, pends, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge limination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Every effo should be made to contain accidental spills of concentrate to the immediate area. This may be accomplished

by the use sandbags or barrier material to confine the spill to facilitate cleanup and disposal. Contaminated sand or barrier materials by disposed of by burial in an approved landfill. Many spills may be cleaned up with rags or other absolute materials by wiping, soaking and/or mopping and allowing the liquid to absorb onto the material. The absorbent material may then be disposed of by incineration or landfill. Floor drains in areas of material use should be protected. In absorbent material or barrier material to contain accidental spills.

Inactivation of solutions containing ÆGIS Antimicrobial may be accomplished by addition of AGNE Elementarity, or detergent quantity equivalent to that of ÆGIS Antimicrobial in solution.

With COMMENTS in EPA Letter Dated:

PHYSIC AL OR CHEMICAL HAZARDS

Flammab Keep away from heat and open flame

WUV 1 9 2003

Under the Federal Insecticide,
Finguish, and Andenticide Act as
an enced for the perticide,
registered under EPA Reg. No. 6 4881-3

PRODUCT FEATURES AND BENEFITS

AEGIS Antimicrobial imparts durable biostatic activity to the surface of a wide variety of substrates.

AEGIS Antimicrobial is effective against mold, mildew and algae as a static agent.

Increased efficiency – through proper application, durable bacteriostatic, fungistatic and algistatic surfaces can be attained with a minimum amount of AEGIS Antimicrobial.

Provides freshness and combats deterioration and discoloration caused by bacteria, fungi and algae.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its label.

FOR COMMERCIAL APPLICATIONS IN HOMES, OFFICES, AUTOMOBILES AND INSTITUTIONS AND FOR INDUSTRIAL USE ONLY. This product is registered as a microbiostatic agent for material preservation only; neither this product nor the articles treated with this product may state or imply any public health claims. Articles or substances treated with this product will be exempt from FIFRA regulation pursuant to 40 CFR 152.25(a) if the intended use for incorporating this material into a treated article or substance is for the protection of the article or substance itself.

add shield

APPROVED USES: AEGIS Antimicrobial is effective against odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew) and algae as a static agent. AEGIS Antimicrobial can be used as a final bacteriostatic finish on the following items to impart bacteriostatic/fungistatic (mold and mildew) activity:

Carpet, Draperies and Upholstery

 Interior Non-Food Contact Hard Surfaces Including: Floors, Walls, Ceilings, Ceramic Tile, Concrete, Chrome, Stainless Steel, Fiberglass, Vinyl, Porcelain, Paper Wall Covering, Wood and Glass Fixtures, Marble, Aluminum, Book Covers, Pictures and Furniture

AEGIS Antimicrobial can also be used to impart biostatic (bacteriostatic/fungistatic/algae static) activity to substrates for the following applications:

Not for Not for homeowern

woodhures

[Add approved uses as finalized for AEM 5700]

HOW TO USE:

MSDS INFORMATION: BEFORE HANDLING, READ PRODUCT AND MATERIAL SAFETY DATA SHEETS AND CONTAINER LABELS FOR SAFE USE, PHYSICAL AND HEALTH HAZARD INFORMATION. THE MATERIAL SAFETY DATA SHEET CAN BE OBTAINED BY WRITING TO ÆGIS ENVIRONMENTS OR BY CALLING (989) 832-8180. A MATERIAL SAFETY DATA SHEET FOR A TYPICAL USE DILUTION AQUEOUS SOLUTION IS ALSO AVAILABLE.

Wear goggles or face shield and rubber gloves when handling the concentrated material. Use with proper ventilation. Undiluted AEGIS Antimicrobial contains 50 percent methanol. Avoid breathing vapors. Keep away from heat and open flame. Methanol is released during mixing, application and drying. If desired, methanol removal may be accelerated by heating dilute solution before treatment of substrate. Appropriate measures should be taken to prevent the accumulation of hazardous concentrations of methanol vapors in the work area. Dry treated areas and articles such as clothing before use. Remove children and pets from treated area until completely dry.

AEGIS Antimicrobial can be applied to organic and inorganic surfaces as a dilute aqueous solution to give 0.1 to 1.0 percent by weight of active ingredients (suggested starting level is 2.5 ounces of AEGIS Antimicrobial to one gallon of water). Aqueous solutions can be prepared by simply adding the antimicrobial agent to water with stirring. NOTICE: Poor agitation when adding this silane to water can result in locally high concentrations, which may form gel particles. Surfaces can be treated with the aqueous solution by brushing, dipping, padding, soaking, spraying or fogging until adequately wet, or applying by foaming techniques. After applying treatment, the surface should be allowed to dry at temperatures from ambient to a maximum of 160°C (320° F) to effect complete condensation of silanol groups and to remove water, solvents and/or traces of methanol from hydrolysis. Open windows and use a fan or other active means of ventilation to remove any methanol vapors from the room.

For Pump Spray Application: Dilute 2.5 ounces of AEGIS Antimicrobial per gallon of water. Using pump sprayer, spray entire area 4-6 inches from the surface making sure the surface is completely covered. Apply and then let stand until dry or let stand 3 minutes and wipe dry with cloth or sponge. If spotting occurs, wipe with moist cloth or sponge. Test for staining and colorfastness of fabrics and carpets by treating and drying a small, concealed area prior to application. When treating coarser substrates, more AEGIS Antimicrobial may be required due to absorption.

For Spray Application: For commercial application equipment, dilute 2.5 ounces of AEGIS Antimicrobial per gallon of water; mix well. Apply and then let stand until dry or let stand 3 minutes and wipe dry with cloth or sponge. If spotting occurs, wipe with moist cloth or sponge. Test for staining and color-fastness of fabrics and carpets by treating and drying a small, concealed area prior to application. When treating coarser substrates, more AEGIS Antimicrobial may be required due to absorption. Dry carpet areas and surfaces before re-entry and dry articles before use.

For Dipping/Soaking Application: Use appropriate sized washbasin or tub for dipping/soaking the item you are treating. Use enough AEGIS Antimicrobial solution to completely submerge item. Dilute 2.5 cunces of AEGIS Antimicrobial per gallon of water; mix well. Completely submerge item in solution for 3 minutes. Remove item and dry. Test for staining and color-fastness of fabrics by treating and drying a small, concealed area prior to application. Do not reuse solution after dipping/soaking. The substrate can be dried at room temperatures or at temperatures to a maximum of 160° C (320° F).

For each application, determine optimum application and drying conditions, such as time and temperature before use. If desired, reapply AEGIS Antimicrobial if odor, staining and discoloration due to bacteria, mold or mildew occur.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

STORAGE: Store in original, tightly closed container in an area inaccessible to children and away from food or feed. Moisture sensitive. Keep tightly closed until ready to use. Reclose tightly after each use. When stored in original, unopened containers at or below 25°C (77°F), AEGIS Antimicrobial has a minimum shelf life of 12 months from date of shipment.

PESTICIDE DISPOSAL: Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for quidance.

CONTAINER DISPOSAL: Do not reuse containers. Do not cut or weld containers. Triple rinse (or equivalent) empty containers. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities., This container will have vapor and/or product residues when emptied. All hazard precautions on label must be observed when handling emptied container.



Sold by:

AEGIS ENVIRONMENTAL MANAGEMENT, INC.

3106 SWEDE AVENUE, MIDLAND, MICHIGAN 48642 U.S.A.

1-989-832-8180

© 1998 AEGIS Environmental Management, Inc.

A trademark of AEGIS Environmental Management, Inc., U.S.A.

MADE IN U.S.A.

NOTICE: AEGIS warrants that the product conforms to its chemical description and is reasonably fit for the purposes stated in the labeling when used in accordance with directions under normal conditions of use; but this warranty of fitness for a particular purpose does not extend to the use of this product contrary to written instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to seller, and buyer assumes the risk of any such use. AEGIS ENVIRONMENTAL MANAGEMENT, INC. SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING THE WARRANTY OF MERCHANTABILITY.



METHANOL SOLUTION UN1230 SHIPPING LIMITATIONS
DOT Classification: Flammable.

MAR - 3 2004

Mr. Timothy C. Moses
President, Antimicrobials & Biocides Division
Nova BioGenetics, Inc.
8601 Dunwoody Pl., Suite 338
Atlanta, GA 30350

don't starged

SUBJECT:

BioShield AM500 I

EPA Registration Number: 75497-2 Application Dated: December 1, 2003 Receipt Date: December 9, 2003

Dear Mr. Timothy C. Moses:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable subject to the conditions listed below.

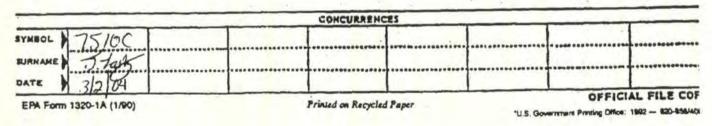
Correct name of Active Ingredient as per Agency request

Conditions

A number of the label comments identified in the Notice of Registration for this product dated 10/13/98 have not been addressed. Make all the revisions listed below to the label for this product.

The following comments apply to the Master Label.

- In future submissions to the Agency, list all packaging sizes on the Application for Pesticide such that the application is in agreement with the label for this product.
 - 2. Revise the "Precautionary Statements" to include: "So not get in eyes or on clothing."



3. So that this label will be in agreement with other similar products already in the market place, add the following statements below the heading: "Directions for Use":

"For use in Formulating, Manufacturing, and Fabricating of Treated Article Products Specified under "approved uses."

AM 500 I may be used in materials that are incorporated into manufactured products listed on this label. The final article may contain from 0.1 to 1.0 % by weight active ingredient."

Add this same language to the collateral label. The land when the collateral label.

4. Add the following two statements directly below the heading "Approved Uses"

"The active ingredient in AM 500 I is effective against fungi (including, mold and and and and and and and and algae as a static agent."

"AM 500 I can be used for incorporation into and treatment of the following items or mildew) and algae as a static agent."

substrates to impart bacteriostatic/fungistatic activity:"

- 5. Revise the use site beginning: "AM500 I can be used in paints and coatings as an in can preservative for ... " by correcting the spelling of preservative. In addition, add this site to the collateral labeling of this product. V
- 6. Add the following statements immediately prior to the Storage and Disposal statements such that this label agrees with the last stamped for this product:

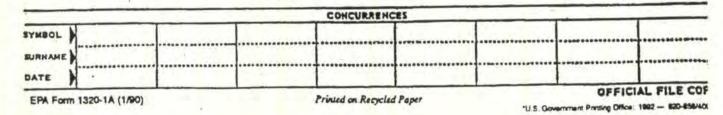
"EPA REGISTRATION REQUIREMENTS:

The applications for which is product is used may require approval by the Environmental Protection Agency on an end-use basis in regard to claims made thereof. Formulators are responsible for satisfying registration requirements for their products."

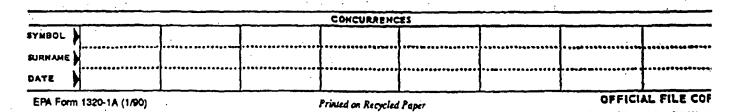
- 7. Make the following revisions to the "Storage and Disposal" statements:
- A. Delete the bracketed information regarding homeowner use as this product is an MUP and not for sale to or use by homeowners.
- B. Revise the Container Disposal statement to read exactly as follows such that the appropriate language is used for metal containers: "Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities."

The following comments apply to the collateral label. Should I will then collateral submit collateral ruled ing?

1. On the first page, revise the statement which begins as follows: "As an active ingredient for formulating microbiocides..." to read "As an active ingredient for formulating microbiostats..." as per the Registration Notice for this product.



- 2. In the description section of the labeling, revise the name of the active ingredient to be in agreement with that listed on the first panel of the Master Label.
- 3. Also in the description section of the labeling, correct the name of this product to read: BioShield AM 500 I.
- 4. Correct the wording in the fifth bullet under Benefits as follows: "...by resisting the growth of odor-causing bacteria and imparts odor resistance."
- 5. Revise to read "Fiberfill for upholstery, sleeping bags, apparel, where the fiber is cotton..." by correcting the spelling of fiberfill and deleting the "etc."
- 6. Add the following site to the collateral labeling such that it is in agreement with the Master Label: "Exterior walls (such as stone, concrete, brick)"
- 7. Add the following clarification to the collateral label: "Polyurethane and cellulose foam for household, industrial and institutional sponges and mops."
- 8. Add the following statement to the Directions for Use as per the Registration Notice for this product: "It is a violation of Federal Law to use this product in a manner inconsistent with its labeling."
- 9. As per the Registration Notice for this product, revise the Precautionary Statements as follows: increase the font size of the signal word "WARNING" and change the statement which reads "Avoid contact with skin or clothing and avoid breathing vapor:" to read "Avoid contact with skin and avoid breathing vapor."
- 10. As per the Registration Notice for this product, revise the Storage and Disposal, Pesticide Storage statement to begin as follows: "Store in original, tightly closed containers below 30° C (86° F) and above 0° C (32° F) in a secure area inaccessible to children and away from food and feed. AM 500 I has a..."
- 11. The Agency suggests that your collateral labeling include a "First Aid" statement which is in agreement with the Master Label for this product.
 - 12. Correct the word "REFRENCES" to read "REFERENCES."



General Comments

A stamped copy of the accepted labeling, including technical bulletin, is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,

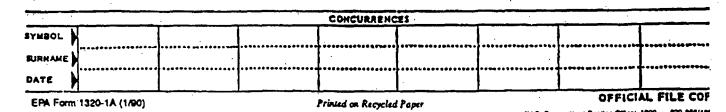
Velma Noble

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510C)

Enclosure: Stamped Label & Technical Bulletin

7510C:T.Lantz:3/1/04:75497-2a



2



MICROBIOSTATIC AGENT BIOSHIELD® AM 500 I

A Silicone Quaternary Ammonium Salt (For Manufacturing Use Only) Other Ingredients:

NGREDIENTS:

TOTAL

Active Ingredient:

3-(trihydroxysilyl) propyldimethyloctadecyl ammonlum chloride.

SIND MINOUTES IN EPA LOHER TOWN

Colorection Products Trades 100 COLL CHICK EPA-ROOM amounted, for a win, and do Pengions, and disciplina MAR 3 2004

95.0%

100.0%

KEEP OUT OF REACH OF CHILDREN

WARNING

EPA EST. xxxxx-Ga-xxxx

Lot No.

NET CONTENTS: 2, 4, 8, 16, 20, 22, or 36 fluid oz.; 1, 5, 55, 150, or 300 gal.

EPA Reg. No. 75497-2

FIRST AID

Have the product container or label with you when calling the poison control center or doctor, or going for treatment.

IF IN EYES:

Hold eye open and rinse slowly and gently with water for 15-20 minutes.

Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.

Call poison control center or doctor for treatment advice.

IF INHALED

Move person to fresh air.

If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.

Call a poison control center or doctor for further treatment advice.

F ON SKIN:

Take off contaminated clothing.

Ringe skin immediately with plenty of water for 15-20 minutes.

Cail a poison control center or doctor for treatment advice.

F SWALLOWED:

Call a poison control conter or doctor immediately for treatment advice.

Have person sip a glass of water if able to swallow.

Do not induce vomiting unless told to do so by a poison control center or doctor.

Do not give anything by mouth to an unconscious person.

A microbiostatic agent is an agent that inhibits the growth of odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae. This product does not protect users or others against food-borne or disease-causing bacteria.

HAZARDS TO HUMANS AND DOMESTIC ANIMALS RECAUTIONARY STATEMENTS

WARNING. Causes substantial but temporary eye injury. Harmful if absorbed through skin or inhaled. Do not get in eyes. Avoid contact with skin and avoid breathing vapor. Wear protective eyewear (goggles or face shield). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or he permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or Regional Office of the EPA.

De-activation may be required during clean up if a spill occurs. De-activation of AM 500l can be achieved by the addition of anionic surfactant (such as soap, sulfonates, sulfates) in quantity equivalent to that of AM 500I.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

AM500I can be incorporated directly into formulations used to make the end products listed under "approved tises"

For formulating use into end use products.

Approved Uses

Under the Testery AP.

AM500 I is approved for use in formulating microbiostats for use in laundry additives, carpet treatment products; upholstery and drapery treatment products.

- Air filters for furnaces, air-conditioners, air purification devices, automobiles, recirculating air handling systems 7
 - Air filters/materials
- Aquarium filter material
- Bed sheats, Nankets, and bedspreads
 - Buffer pads (abrasive and polishing)
- Carpets and draperies
- Exterior walls (such as stone, concrete, brick)
- iberfill for upholstery, steeping bags, apparel, where the fiber is cotton, natural down, nylon, polyester, rayon, or wool
 - Fiberglass ductboard
- Fire hose fabric
- Humidifier belts
- Mattress pads and ticking
- Mens underwear and outerwear

- Non-woven disposable diapers
 - Non-woven polveste
- Outerwear apparel (jackets, sweaters, sweatshirts, coats, raincoats, overcoats, jerseys, ponchos)
 - Disposable polyurethane foam cushions for Lapidus Airfloat Systems;
- and coatings include: latex indoor/outdoor paints and stains, woodstains, architectural paints, laquer and maintenance coatings, AM500l can be used in paints and coatings as an in can presertive for protection of paint film and coating film. Types of paints polyester coatings, gel coatings, amino resins, resins used as additive mixes for cement, epoxy laminating resins, and blends coatings, architural coatings and overlays, anti-corrosion coatings, fire-resistant coatings, aliphatic coatings, vinylester and films, laminates and finishes including alkyd, urethane, enamel, epoxy, siloxaline , amino resins, textile coatings, extrusion and copolymers thereof;
 - Polyurethane and cellulose foam for household, industrial, and institutional sponges and mops
 - Polyurethane and polyethylene foam, when covered
- Polyurethane foam for packaging and cushioning in non-food contact applications
 - Polyurethane foam used as a growth medium for non-food crops and plants
- Pre-moistened towelettes and tissue wipes (these do not impart pesticidal properties)
- Roofing materials defined as shingles, roofing granules, wood shakes, felt, stone and synthetic overcoats
 - Sand bags, tents, tarpaulins, sails, and ropes
 - Athletic and casual shoes
- Shoe insoles
- Shower curtains
- Socks comprised of nylon, nylon/orlon, cotton/nylon, linen/Lycra, acrylic/polypropylene/nylon/Lycra, wool/silk/nylon/Lycra and wool/acrylic/nylon/Lycra
- Throw rugs
- oweling made of 100 percent cotton, 100 percent polyester, and blends of the two fibers
 - Toilet tank and seat covers
 - Umbrellas
- Upholstery made of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polyolefins, polypropylene, rayon, spandex, vinyl, wool
- Vacuum cleaner bags and filters
- Vinyl paper-wallpaper for non-food contact surfaces
- Disposable wiping cloths that can be used for multiple purposes such as dusting or washing furniture, cars, walis, windows, loors, appliances, dishes, counter tops; the wiping cloths do not impart pesticide properties
 - Women's hosiery
- Women's intimate apparel



STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in original, tightly closed containers below 30°C (86°F) and above 0°C (32°F) in a secure area inaccessible o children and away from food or feed

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal

landfill, or incineration, or, if allowed by state and focal authorities, by burning. If burned, stay out of smoke. [For homeowner use Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary statement will read: "Container Disposal: Securely wrap original container in several layers of newspaper and discard in trash."]

MSDS CAN BE OBTAINED BY WRITING Nova BioGenetics Inc. 8601 Dunwoody Place, Suite 338, Atlanta, Georgia 30350 or obtain from our FOR MORE INFORMATION CONCERNING THIS PRODUCT, PLEASE CONSULT THE MATERIAL SAFETY DATA SHEET (MSDS). THE website www.novabiogenetics.com

MPORTANT: WARRANTY AND DISCLAIMER INFORMATION

when used in accordance with directions under normal conditions of use; but this warranty of fitness for a particular purpose does not extend to the use of this product contrary to bulletin instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to the seller, and Nova BioGenetics Inc., warrants that the product conforms to its chemical description and is reasonably fit for the purposes stated in this bulletin buyer assumes the risk of any such use.

NOVA SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING THE WARRANTY OF MERCHANTABILITY

Under the Forbach Forbach Burgicials, and Rodan Forbach Burgicials for the positions, fegistered under EPA Forb. No.

MAR & ZONA



Collateral Labeling

NovaBioGenetics Inc. 8601 Dunwoody Place, Suite 338 Atlanta, GA 30350

Information About

Microbiostatic Agents

AM500 I- FOR MANFACTURING USE ONLY

U.S. Environmental Protection

TYPICAL PROPERTIES

These values are not intended for use in preparing specifications

CH₃[(CH₃O)₃Si(CH₂)₃N-C₁₈H₃₇]+Cl hatel insecticide, CH₃ ं ई Rodenticide Act as Concentration......5.0% a the pesticide, ac: EPA Reg. No. 75497-2 Solubility......Miscible in all Proportions with Water, ethanol, and methanolStable to 230C Thermal Stability Specification Writers: Please contact NovaBioGenetics for information regarding specifications

DESCRIPTION

AM500 I is NovaBioGenetics field's designation for 3-(trimethoxysilyl) propyloctdimethyl ammonium chloride containing 5 percent active ingredient by weight. Alkoxysilanes of this nature have been shown to form durable bonded coatings to a number of materials (see "References" section).

AM500 I offer users the following features:

- Good durability NOVABIOGENETICS AM500 I imparts biostatic activity to the surface of a wide variety of substrates
- Increased efficiency-through proper application, durable bacteriostatic, fungi static and algistatic surfaces can be attended with a minimum amount of AM500I.

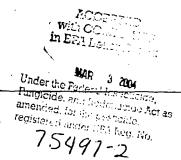
BENEFITS

The following benefits are derived when a formulation containing the active ingredient is applied to a surface:

- Provides freshness and combats deteration caused by bacteria, fungi, and algae.
- Inhibits growth of bacteria and mildew on the treated article.
- Prolongs the life of an article by inhibiting the growth of bacteria and mildew.
- Resists development of bacterial and fungal odors.
- Retains freshness by resisting the growth of odor-causing bacteria growth and imparts odor resistance.
- Product performance with little degradation up to 375 F

Materials treated with formulations containing the microbiostatics agent AM500 I are preserved by the bacteriostatic, fungistatic and algistatic action imparted by the active ingredient. AM500 I inhibit the growth of microorganisms that are responsible for causing odor, discoloration, and deteration. It also provides residual inhibition of microorganisms to aid in the control of these deleterious effects. AM500 I

forms a coating on a wide variety of substrates and microbiostatic action is exhibited on contact.



APPROVED USES

AM500 I is approved for use in formulating microbiostats for use in laundry additives, carpet treatment products, upholstery and drapery treatment products.

The active ingredient in AM500 I is an effective agent against fungi (including mold and mildew) and algae as a static agent.

AM500 I can be used for incorporation into and treatment of the following items or substrates to impart bacteriostatic/fungistatic activity.

- Air filters for furnaces, air-conditioners, air purification devices, automobiles, recirculation air handling systems;
- Air filters/materials:
- Aquarium filter materials;
- Bed sheets, blankets, and bedspreads;
- Buffer pads(abrasive and polishing):
- Carpets and draperies;

- Fiberfil led for upholstery, sleeping bags, apparel, etc., where the fiber is cotton, natural down, nylon, polyester, rayon, or wool;
- Fire hose fabric;
- Fiberglass duct board:
- Humidifier belts;
- Mattress pads and ticking:
- Men's underwear and outerwear;
- Non-woven disposable diapers:
- Non-woven polyester;
- Outerwear apparel:
- Disposable polyurethane foam cushions for Lapidus Air float Systems;
- Polycretiane foam for household, industrial, and instructional sponges and mops;
- Polyurethane and polyethylene foam, when covered;
- Polyurethane foam for packaging and cushioning in non-food contact applications;
- Polyurethane foam used as a growth medium for non-food crops and plants;
- Pre-moistened towelettes and tissue wipes (these do not impart pestical properties);
- Roofing materials- defied as shingles, roofing granules, wood shakes, felt, stone and synthetic overcoats;
- Sandbags, tents, tarpaulins, sails, and ropes;
- Athletic and casual shoes;
- Shoe insoles:
- Shower curtains:
- Socks compromised of nylon, nylon/orion, cotton/nylon, linen/Lycra, and acrylic/polypropylene/nylon. Lycra, wool/silk/nylon/Lycra and wool/acrylic/nylon/Lycra,
- Throw rugs;
- Toweling made of 100 percent cotton, 100 percent polyester, and blends of the two fibers;
- Toilet tank and seat covers;
- Umbrellas:
- Upholstery made of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polyolefin's, polypropylene, rayon, spandex, vinyl, and wool;
- Vacuum cleaner bags and filters;
- Vinyl paper-wallpaper for non-food contact surfaces;
- Disposable wiping cloths that can be used for multiple purposes such as dusting or washing furniture, cars, walls, windows, floors, appliances, dishes, counter tops, etc.; the wiping cloths do not impart pesticide properties;
- Women's hosiery;
- Women's imitate apparel.

DIRECTIONS FOR USE

AM500 I can be incorporated directly into formulations used to make the end products listed in this bulletin.

PRECAUTIONARY STATEMENTS

75447-5 465 Warning Causes substantial but temporary eye injury. Harmful if absorbed through skin or inhaled. Do not get in eyes or clothing. Avoid contact with skin or clothing and avoid breathing vapor. Wear protective eyewear (goggles or face shield). Wash thoroughly with soap and water after handling. Remove contained clothing and wash clothing before reuse.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant

Discharge Elimation System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

Inactivation of solutions containing AM500 I may be accomplished by one of the following methods:

- Addition of an anionic surfactant or detergent in quantity equivalent to that of AM500 I in solution;
- Addition of Triton X-100 nonionic detergent at a final concentration of 10,000 ppm (1.0 percent volume/volume) or greater to bath solutions up to 1.0 percent volume/volume of AM500 I.

Every effort should be made to contain accidental spills of AM500 I to the immediate area. This may be accomplished by the use of sandbags to confine the spill to facilitate cleanup and disposal. Contaminated sand may then be disposed of by burial in an approved landfill. Many spills may be cleaned up with rags by wiping and/or moping and allowing the liquid to absorb into the fabric. The rags may then be disposed of by incineration.

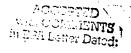
Floor drains in areas of material use should be protected with sandbags to contain accidental spills.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in original, unopened containers below 3 C (86 F) and above 0 C (32 F). AM500 I have minimum shelf life of 12 months from the date of shipment from NovaBioGenetics

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.



#AR 3 2004

Container Disposal: [plastic] Triple rinse (or equivalent). Then offer for recycling or recondition, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. [Metal] Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

75497-2

Before handling, read product label in its entirety

IMPORTANT: WARRANTY AND DISCLAIMER INFORMATION

Nova Biogenetics Technologies, Inc., warrants that the product conforms to its chemical description and is reasonably fit for the purposes stated in this bulletin when used in accordance with directions under normal conditions of use; but this warranty of fitness for a particular purpose does not extend to the use of this product contrary to bulletin instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to seller, and buyer assumes the risk of any such use.

NOVA BIOGENETICS SPECFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING THE WARRANTY OF MERCHANTABILTY.

REFRENCES

- 1. Hough, J.S. and Lyons, T.P. "Coupling of Enzymes onto Microorganisms" Nature. London, 1972, 235:389.
- 2. Johannes, O.K., Stark, F.O., Voguel, G.E., and Fleischmann, R.M. "Evidence for Chemical Bond Formation at Silane Coupling Agent Interfaces." J. Compos. Master. 1967,1:278-292.
- 3. Plueddemann, E.P. "Adhesion through Silane Coupling Agents." J. Adhesion, 1970, 2:184-201.
- 4. Venter, J.C., Dixion, J.E., Maroko, P.R., and Kaplan, N.O. "Biologically Active Catecholamine Covalently Bound to Glass Beads." Proc. Nat. Acad. Sci. (U.S.A.), 1972, 69: 1141-1145.
- 5. Weetall, H.H. "1 rypsin and Papuan Covalently Coupling to Porous Glass." Science, 1969, 166: 615-617.
- 6. Isquith, A.J., Abbott, E.A., and Walters, P.A. "Surface-Bonded Antimicrobial Activity of an Organosilicon Quaternary Ammonium Chloride." Appl. Microbial., 1972, 24; 859-863.
- 7. Getting, R.L. and Triplett, B.L. "A New Durable Antimicrobial Finish for Textiles." AATCC Book of Papers-1978 Nat. Tech. Conf., 1978, 259-261.
- 8. Isquith, A.J. and McCallum, C.J, "Surface Kinetic Test Method for Determining Rate of Kill by an Antimicrobial Solid." Appl. & Environ. Microbial. 1978, 36: 700-704.
- 9. Malek, J.R. and Speier, J.L. "Development of an Organosilicone Antimicrobial Agent for the Treatment of Surfaces." J. Coated Fabrics, 1992, 12:38-45.
- 10. Siddiqui, W.H., Malek, J.R., Santon, E., and Hobbs, E.J. "Percutaneous Absorbation of an Antimicrobial Organosilicon Quaternary Ammonium Chloride in Rabbits." J. Appl. 1983, 3.3:146-149.
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- 12. McGee, J.G., Malek, J.R., and White, W.C. "New Antimicrobial Treatment for Carpet Applications." Am. Dyestuff Rep., 1983, 6:56-59.
- 13. Hales J.G., Sofkin, M.E., and White, W.C. "Antimicrobial Treatments, Part 1: What They Are and Why They Are Used." Cleaning and Restoration." 1986, March, 14-15.
- 14. Hales, M.G. and White, W.C. "Antimicrobial Treatments, Part 2: Types and Considerations for Use." Cleaning and Restoration." 1986, Vol. 24, Num.4, 13-15.
- 15. Hales, M.G. and White, W.C. "Antimicrobial Treatments, Part 3: Methods for Determining Their Effectiveness." Cleaning and Restoration", 1986. May, 18-20.
- 16. Battice, D.R. and Hales, M.G. "A New Technology for Producing Stabilized Foams Having Antimicrobial Activity." Journal of Cellular Plastics, 1985, Vol. 21, Num.5, 332-337.

NovaBioGenetics Inc. 8601 Dunwoody Place. Suite 338 Atlanta, GA 30350

ACCEPTED
with COMMENTS
in EPA Letter Dated:
MAR 3 2004

Under the Foliarel Insecticitie, fungicide, and Roder for the Agras an ended, for the posteride, registered under EPA Reg. No.

75497-2



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

August 12, 2004

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

KIMBERLY CASPERSON/TIMOTHY C. MOSES NOVA BIOGENETICS, INC. 8601 DUNWOODY PLACE, SUITE 338 ATLANTA, GA 30350

PRODUCT NAME: BIOSHIELD AM 500 I

COMPANY NAME: NOVA BIOGENETICS, INC.

EPA FILE SYMBOL: 75497-2 EPA RECEIPT DATE: 08/06/04

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Antimicrobials Division, Risk Management Team 31, at (703) 308-6233.

Sincerely,

7 Wrise

Front End Processing Staff

Information Services Branch

Information Resources and Services Division



August 3, 2004

U.S. Environmental Protection Agency OPP Document Processing 7504C, AD, Ariel Rios Building 1200 Pennsylvania Ave., NW Washington, D.C. 20460

SUBJECT: BioShield AM 500I

EPA Registration No. 75497-2 Master Label - Amendment

Dear Ms. Tracy Lantz:

In connection with registration under the FIFRA 3(c)(7)(A), the master and collateral labels have been combined for simplification. Further additions and clarifications have been made for clearer understanding. As noted on the attached EPA Form 8570-1, all revisions and additions are made in blue.

The following lists specific additions/changes made of note:

- · Microbiostatic Agent corrected to Antimicrobial Agent
 - Please refer to AEGIS EPA No. 64881-3 (attached), which has the same active ingredient and is also based on the same Dow technology.
- Additional uses were added, which are identical to our attached AM500 (75497-1) master label amendment submission dated 7/28/04.

Please call me, or Tim Moses if I'm unavailable, at 770-650-6508 should you have any. questions.

Sincerely.

Kimberly Casperson General Manager

Nova BioGenetics Inc.

\$EPA	United States Environmental Protection Agency Washington, DC 20460				1	Regist Amend Other		OPP Identifier Number 75497	
		Application	n for Pestic	ide - Sec	tion	L			
Company/Product Number Nova BioGenetics Inc.				2. EPA Product Manager Velma Noble 3. Proposed € ✓ None			roposed Classification		
4. Company/Product (Name BioShield AM 5001			PM# 31						
5. Name and Address of Ap 8601 Dunwoody Pl., Atlanta, GA 30350		ode)	(b)(i), to: EPA	my product Reg. No.	is sim	nilar or ide 97-2	ntical in co	FIFRA Section 3(c)(3) emposition and labeling	
Check if this	s is a new address		Prod	uct Name	BioS	Shield Al	M 5001		
			Section -						
Resubmission in responsion in responsion in responsion in responsion in responsion in responsion in Confection with registratic clarifications have been made attached letter in based on the same Dow techniques.	below. nal page(s) if necessary under the FIFRA 3(defect for clearer understary toting specific additions	ry. (For sections)(7)(A), the mas	ter and collateral la ter label. All revis	Agency let "Me Too" Other - Exp bels have bee ions and addit	Applicolain ben comions ar	ation. elow. bined for sire in blue.	nplification.		
			Section -	III	_				
1. Material Thie Product Wi	I Be Packaged in:								
Child-Resistant Packaging Yes ✓ No Volume Yes No		No. per	Water Soluble Packaging Yes ✓ No If "Yes" No. pe				Metal Plastic Glass Paper	Metal Plastic Glass	
* Certification must be submitted	Unit Packaging wgt 2, 4, 8, 16, 20, 22,		Package wgt	containe	or		Other (Specify)	
3. Location of Net Contents	The state of the s	4. Size(s) Ret	tell Container N/A		5. La	1	abel Direction	ons ch container	
6. Manner in Which Label is	Affixed to Product	J Lithog Paper Stenci	raph glued led	Othe	or				
			Section -	IV					
1. Contact Point (Complete	items directly below	for identification	n of individual to	be contacted,	if nec	essary, to	process this	s application.)	
Name Kimberly Casperson/Timothy C. Moses			Title General Manag	ral Manager/SVP and COO Telephone No. (Include of 770-650-6508****			e No. (Include Area Code)		
I certify that the state			all attachments t					6. Date Application Repbived (Stamped)	

both under applicable law.

3. Title

General Manager

4. Typed Name Kimberly Casperson

8/3/04



March 10, 2004

U.S. Environmental Protection Agency OPP Document Processing 7504C, AD, Ariel Rios Building 1200 Pennsylvania Ave., NW Washington, D.C. 20460

SUBJECT:

BioShield AM500 I

EPA Registration No. 75497-2 Master and Collateral Labels - Final

Dear Ms. Tracy Lantz:

Per a letter from Ms. Noble, dated March 3, 2004, the Master Label and Collateral Label/Technical Bulletin for BioShield AM500 I are enclosed with the requested revisions/conditions.

Please call me, or Tim Moses if I'm unavailable, at 770-650-6508 should you have any questions.

Sincerely,

Kimberly Casperson
General Manager

In Accordance with PR Notice 8202 Based On Draft Labeling Dated

Nova BioGenetics Inc.

8601 Dunwoody Place, Suite 338, Atlanta, Georgia 30350 Ph: 770-650-6508 Fax: 770-650-0411



BIOSHIELD® AM 500 I MICROBIOSTATIC AGENT

A Silicone Quaternary Ammonium Salt (For Manufacturing Use Only)

Active Ingredient: Other Ingredients:	Octadecylaminodimethyltrihydroxysilyl propyl ammonium chloride	5.0% 95.0%
IOTAL INGREDIENTS:	KEEP OUT OF REACH OF CHILDREN	100.0%

EPA Reg. No. 75497-2

WARNING

EPA EST. xxxxx-Ga-xxxx

Lot No.

NET CONTENTS: 2, 4, 8, 16, 20, 22, or 36 fluid oz.; 1, 5, 55, 150, or 300 gal.

FIRST AID

Have the product container or label with you when calling the poison control center or doctor, or going for treatment.

IF IN EYES:

Hold eye open and rinse slowly and gently with water for 15-20 minutes.

Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.

Call poison control center or doctor for treatment advice.

IF INHALED:

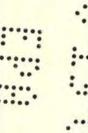
- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.
 - Call a poison control center or doctor for further treatment advice.

IF ON SKIN:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.



A microbiostatic agent is an agent that inhibits the growth of odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae. This product does not protect users or others against food-borne or disease-causing bacteria

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING. Causes substantial but temporary eye injury. Harmful if absorbed through skin or inhaled. Do not get in eyes or on clothing. Avoid contact with skin and avoid breathing vapor. Wear protective eyewear (goggles or face shield). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the

De-activation may be required during clean up if a spill occurs. De-activation of AM 500I can be achieved by the addition of anionic surfactant (such as soap, sulfonates, sulfates) in quantity equivalent to that of AM 5001.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

AM500I may be used in materials that are incorporated into manufactured products listed on this label. The final article may contain from For use in Formulating, Manufacturing, and Fabricating of Treated Article Products Specified under "approved uses." 0.1 to 1.0% by weight active ingredient.

Approved Uses

AM500 I is approved for use in formulating microbiostats for use in laundry additives, carpet treatment products, upholstery and drapery treatment products. AM 500I can be used for incorporation into and treatment of the following items or substrates to impart bacteriostatic/fungistatic activity. The active ingredient in AM 500I is effective against fungi (including mold and mildew) and algae as a static agent.

- Air filters for furnaces, air-conditioners, air purification devices, automobiles, recirculating air handling systems
- Air filters/materials
- Aquarium filter material
- Bed sheets, blankets, and bedspreads
- Buffer pads (abrasive and polishing)
- Carpets and draperies
- Exterior walls (such as stone, concrete, brick)
- Fiberfill for upholstery, sleeping bags, apparel, where the fiber is cotton, natural down, nylon, polyester, rayon, or wool
- Fiberglass ductboard
- Fire hose fabric
- Humidifier belts
- Mattress pads and ticking
- Mens underwear and outerwear
- Non-woven disposable diapers
 - Non-woven polyester
- Outerwear apparel (jackets, sweaters, sweatshirts, coats, raincoats, overcoats, jerseys, ponchos)
- Disposable polyurethane foam cushions for Lapidus Airfloat Systems;
- AM500I can be used in paints and coatings as an in can preservative for protection of paint film and coating film. Types of paints and architural coatings and overlays, anti-corrosion coatings, fire-resistant coatings, aliphatic coatings, vinylester and polyester coatings, gel coatings, amino resins, resins used as additive mixes for cement, epoxy laminating resins, and blends and copolymers thereof; coatings include : latex indoor/outdoor paints and stains, woodstains, architectural paints, laquer and maintenance coatings, films, laminates and finishes including alkyd, urethane, enamel, epoxy, siloxaline, amino resins, textile coatings, extrusion coatings,
 - Polyurethane and cellulose foam for household, industrial, and institutional sponges and mops
- Polyurethane and polyethylene foam, when covered
- Polyurethane foam for packaging and cushioning in non-food contact applications
 - Polyurethane foam used as a growth medium for non-food crops and plants
- Pre-moistened towelettes and tissue wipes (these do not impart pesticidal properties)
- Roofing materials defined as shingles, roofing granules, wood shakes, felt, stone and synthetic overcoats
 - Sand bags, tents, tarpaulins, sails, and ropes
- Athletic and casual shoes
- Shoe insoles
- Shower curtains
- Socks comprised of nylon, nylon/orlon, cotton/nylon, linen/Lycra, acrylic/polypropylene/nylon/Lycra, weof st wool/acrylic/nylon/Lycra
- Throw rugs
- Toweling made of 100 percent cotton, 100 percent polyester, and blends of the two fibers
 - Toilet tank and seat covers

- Umbrellas
- Upholstery made of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polyolefins, polypropylene, rayon, spandex, vinyl, wool
- Vacuum cleaner bags and filters
- Vinyl paper-wallpaper for non-food contact surfaces
- Disposable wiping cloths that can be used for multiple purposes such as dusting or washing furniture, cars, walls, windows, floors, appliances, dishes, counter tops; the wiping cloths do not impart pesticide properties
 - Women's hosiery
- Women's intimate apparel

EPA REGISTRATION REQUIREMENTS:

The applications for which this product is used may require approval by the Environmental Protection Agency on an end-use basis in regard to claims made thereof. Formulators are responsible for satisfying registration requirements for their products.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in original, tightly closed containers below 30°C (86°F) and above 0°C (32°F) in a secure area inaccessible to children and away from food or feed

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities. FOR MORE INFORMATION CONCERNING THIS PRODUCT, PLEASE CONSULT THE MATERIAL SAFETY DATA SHEET (MSDS). THE MSDS CAN BE OBTAINED BY WRITING Nova BioGenetics Inc. 8601 Dunwoody Place, Suite 338, Atlanta, Georgia 30350 or obtain from our website www.novabiogenetics.com

used in accordance with directions under normal conditions of use; but this warranty of fitness for a particular purpose does not extend to the use of this product contrary to bulletin instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to the seller, and buyer assumes the risk of any such use.

Nova SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING THE WARRANTY OF MERCHANTABILITY. IMPORTANT: WARRANTY AND DISCLAIMER INFORMATION

Nova BioGenetics Inc., warrants that the product conforms to its chemical description and is reasonably fit for the purposes stated in this bulletin when



Collateral Labeling

Nova BioGenetics Inc. 8601 Dunwoody Place, Suite 338 Atlanta, GA 30350

Information About

Microbiostatic Agents

AM500 I - FOR MANFACTURING USE ONLY

U.S. Environmental Protection Agency Re	gistration Number75497-2
Type	Silicone quaternary ammonium salt
Physical Form.	
Special Properties	
Primary Uses	As an active ingredient for
Formulating microbiostats for use in laundry additi	ves,
Carpet treatment products, upholstery and	
Drapery treatment products to give a	
Bacteriostatic, fungistatic, mildewstatic activity	

TYPICAL PROPERTIES

These values are not intended for use in preparing specifications

••••	CH ₃
•::::•	
Structure[(C	CH ₃ O) ₃ Si(CH ₂) ₃ N-C ₁₈ H ₃₇]+Cl
	CH ₃
Concentration	5.0%
Appearance	
Solubility	
Proportions with	
Water, ethanol, and methanol	
Thermal Stability	Stable to 230C
Specification Writers: Please contact 1	Nova BioGenetics for information regarding specifications

DESCRIPTION

BioShield AM500 I is Nova BioGenetics' fields designation for octadecylaminodimethyltrihydroxysilyl propyl ammonium chloride containing 5 percent active ingredient by weight. Alkoxysilanes of this nature have been shown to form durable bonded coatings to a number of materials (see "References" section).

AM500 I offers users the following features:

- Good durability –NOVA BIOGENETICS AM500 I imparts biostatic activity to the surface of a wide variety of substrates.
- Increased efficiency-through proper application, durable bacteriostatic, fungi static and algistatic surfaces can be attained with a minimum amount of AM500I.

BENEFITS

The following benefits are derived when a formulation containing the active ingredient is applied to a surface:

- Provides freshness and combats deterioration caused by bacteria, fungi, and algae.
- Inhibits growth of bacteria and mildew on the treated article.
- Prolongs the life of an article by inhibiting the growth of bacteria and mildew.
- Resists development of bacterial and fungal odors.
- Retains freshness by resisting the growth of odor-causing bacteria and imparts odor resistance.
- Product performance with little degradation up to 375 F

Materials treated with formulations containing the microbiostatic agent AM500 I are preserved by the bacteriostatic, fungistatic and algistatic action imparted by the active ingredient. AM500 I inhibit the growth of microorganisms that are responsible for causing odor, discoloration, and deterioration. It also provides residual inhibition of microorganisms to aid in the control of these deleterious effects. AM500 I

forms a coating on a wide variety of substrates and microbiostatic action is exhibited on contact.

APPROVED USES

AM500 I is approved for use in formulating microbiostats for use in laundry additives, carpet treatment products, upholstery and drapery treatment products.

The active ingredient in AM500 I is an effective agent against fungi (including mold and mildew) and algae as a static agent.

AM500 I can be used for incorporation into and treatment of the following items or substrates to impart bacteriostatic/fungistatic activity.

- Air filters for furnaces, air-conditioners, air purification devices, automobiles, recirculation air handling systems;
- Air filters/materials;
- · Aquarium filter materials;
- · Bed sheets, blankets, and bedspreads;
- Euffer pads(abrasive and polishing);
- Carpets and draperies;
- Exterior walls (such as stone, concrete, brick)
- Fiberfill for upholstery, sleeping bags, apparel, where the fiber is cotton, natural down, nylon, polyester, rayon, or wool;
- · Fire hose fabric;

PRECAUTIONARY STATEMENTS

Warning: Causes substantial but temporary eye injury. Harmful if absorbed through skin or inhaled. Do not get in eyes or clothing. Avoid contact with skin and avoid breathing vapor. Wear protective eyewear (goggles or face shield). Wash thoroughly with soap and water after handling. Remove contained clothing and wash clothing before reuse.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

Inactivation of solutions containing AM500 I may be accomplished by one of the following methods:

- Addition of an anionic surfactant or detergent in quantity equivalent to that of AM500 I in solution;
- Addition of Triton X-100 nonionic detergent at a final concentration of 10,000 ppm (1.0 percent volume/volume) or greater to bath solutions up to 1.0 percent volume/volume of AM500 I.

Every effort should be made to contain accidental spills of AM500 I to the immediate area. This may be accomplished by the use of sandbags to confine the spill to facilitate cleanup and disposal. Contaminated sand may then be disposed of by burial in an approved landfill. Many spills may be cleaned up with rags by wiping and/or moping and allowing the liquid to absorb into the fabric. The rags may then be disposed of by incineration.

Floor drains in areas of material use should be protected with sandbags to contain accidental spills.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in original, tightly closed containers below 30° C (86° F) and above 0° C (32° F) in a secure area inaccessible to children and away from food and feed. AM500 I has a minimum shelf life of 12 months from the date of shipment from Nova BioGenetics.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: [plastic] Triple rinse (or equivalent). Then offer for recycling or recondition, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. [Metal] Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.



FIRST AID

Have the product container or label with you when calling the poison control center or doctor, or going for treatment.

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call poison control center or doctor for treatment advice.

IF INHALED:

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-tomouth, if possible.
- Call a poison control center or doctor for further treatment advice.

IF ON SKIN:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

REFERENCES

- Hough, J.S. and Lyons, T.P. "Coupling of Enzymes onto Microorganisms" Nature. London, 1972, 235:389.
- Johannes, O.K., Stark, F.O., Voguel, G.E., and Fleischmann, R.M. "Evidence for Chemical Bond Formation at Silane Coupling Agent Interfaces." J. Compos. Master. 1967,1:278-292.
- 3. Plueddemann, E.P. "Adhesion through Silane Coupling Agents." J. Adhesion, 1970, 2:184-201.
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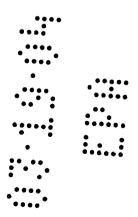
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IMPORTANT: WARRANTY AND DISCLAIMER INFORMATION

Nova Biogenetics Technologies, Inc., warrants that the product conforms to its chemical description and is reasonably fit for the purposes stated in this bulletin when used in accordance with directions under normal conditions of use; but this warranty of fitness for a particular purpose does not extend to the use of this product contrary to bulletin instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to seller, and buyer assumes the risk of any such use.

NOVA BIOGENETICS SPECFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING THE WARRANTY OF MERCHANTABILTY.

Nova BioGenetics Inc. 8601 Dunwoody Place. Suite 338 Atlanta, GA 30350



DECISION: 336608 Sub MISSION: 750639

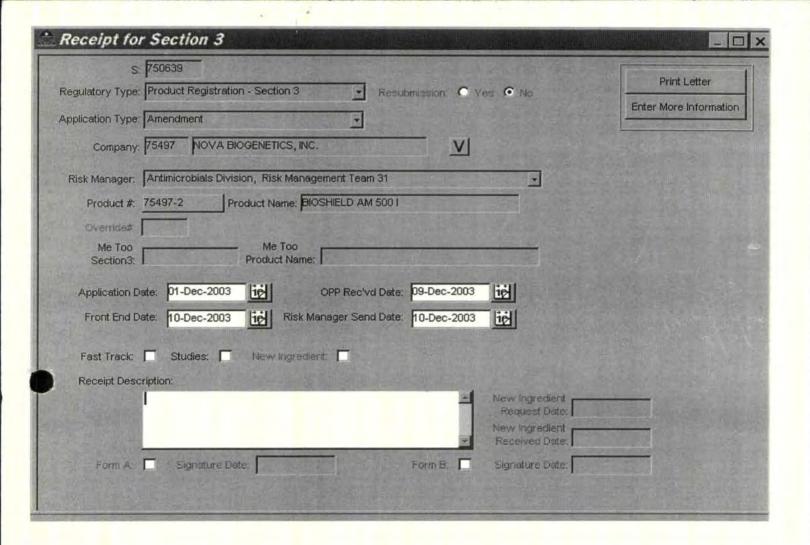
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PM WORK ASSIGNMENT SHEET

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COMMENTS

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MAR - 3 2004

Mr. Timothy C. Moses
President, Antimicrobials & Biocides Division
Nova BioGenetics, Inc.
8601 Dunwoody Pl., Suite 338
Atlanta, GA 30350

SUBJECT:

BioShield AM500 I

EPA Registration Number: 75497-2 Application Dated: December 1, 2003 Receipt Date: December 9, 2003

Dear Mr. Timothy C. Moses:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable subject to the conditions listed below.

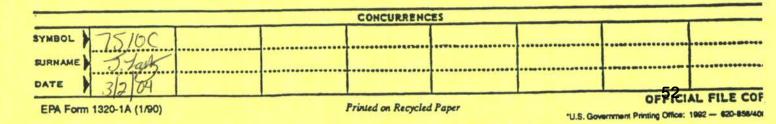
Correct name of Active Ingredient as per Agency request

Conditions

A number of the label comments identified in the Notice of Registration for this product dated 10/13/98 have not been addressed. Make all the revisions listed below to the label for this product.

The following comments apply to the Master Label.

- 1. In future submissions to the Agency, list all packaging sizes on the Application for Pesticide such that the application is in agreement with the label for this product.
 - 2. Revise the "Precautionary Statements" to include: "So not get in eyes or on clothing."



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

3. So that this label will be in agreement with other similar products already in the market place, add the following statements below the heading: "Directions for Use":

"For use in Formulating, Manufacturing, and Fabricating of Treated Article Products Specified under "approved uses."

AM 500 I may be used in materials that are incorporated into manufactured products listed on this label. The final article may contain from 0.1 to 1.0 % by weight active ingredient."

Add this same language to the collateral label.

4. Add the following two statements directly below the heading "Approved Uses"

"The active ingredient in AM 500 I is effective against fungi (including, mold and mildew) and algae as a static agent."

"AM 500 I can be used for incorporation into and treatment of the following items or substrates to impart bacteriostatic/fungistatic activity:"

- 5. Revise the use site beginning: "AM500 I can be used in paints and coatings as an in can *preservative* for..." by correcting the spelling of preservative. <u>In addition, add this site to the collateral labeling of this product.</u>
- 6. Add the following statements immediately prior to the Storage and Disposal statements such that this label agrees with the last stamped for this product:

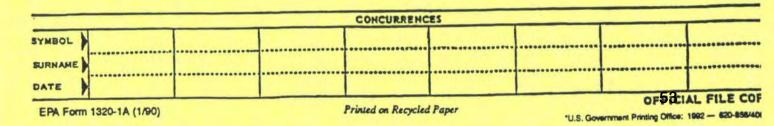
"EPA REGISTRATION REQUIREMENTS:

The applications for which is product is used may require approval by the Environmental Protection Agency on an end-use basis in regard to claims made thereof. Formulators are responsible for satisfying registration requirements for their products."

- 7. Make the following revisions to the "Storage and Disposal" statements:
- A. Delete the bracketed information regarding homeowner use as this product is an MUP and not for sale to or use by homeowners.
- B. Revise the Container Disposal statement to read exactly as follows such that the appropriate language is used for metal containers: "Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities."

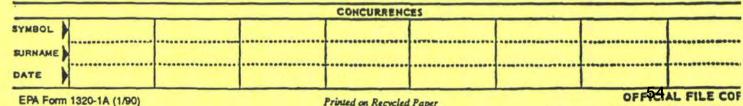
The following comments apply to the collateral label.

1. On the first page, revise the statement which begins as follows: "As an active ingredient for formulating microbiocides..." to read "As an active ingredient for formulating microbiostats..." as per the Registration Notice for this product.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

- 2. In the description section of the labeling, revise the name of the active ingredient to be in agreement with that listed on the first panel of the Master Label.
- 3. Also in the description section of the labeling, correct the name of this product to read: BioShield AM 500 I.
- 4. Correct the wording in the fifth bullet under Benefits as follows: "...by resisting the growth of odor-causing bacteria and imparts odor resistance."
- 5. Revise to read "Fiberfill for upholstery, sleeping bags, apparel, where the fiber is cotton..." by correcting the spelling of fiberfill and deleting the "etc."
- 6. Add the following site to the collateral labeling such that it is in agreement with the Master Label: "Exterior walls (such as stone, concrete, brick)"
- 7. Add the following clarification to the collateral label: "Polyurethane and cellulose foam for household, industrial and institutional sponges and mops."
- 8. Add the following statement to the Directions for Use as per the Registration Notice for this product: "It is a violation of Federal Law to use this product in a manner inconsistent with its labeling."
- 9. As per the Registration Notice for this product, revise the Precautionary Statements as follows: increase the font size of the signal word "WARNING" and change the statement which reads "Avoid contact with skin or clothing and avoid breathing vapor." to read "Avoid contact with skin and avoid breathing vapor."
- 10. As per the Registration Notice for this product, revise the Storage and Disposal, Pesticide Storage statement to begin as follows: "Store in original, tightly closed containers below 30° C (86° F) and above 0° C (32° F) in a secure area inaccessible to children and away from food and feed. AM 500 I has a ... "
- 11. The Agency suggests that your collateral labeling include a "First Aid" statement which is in agreement with the Master Label for this product.
 - 12. Correct the word "REFRENCES" to read "REFERENCES."



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

General Comments

A stamped copy of the accepted labeling, including technical bulletin, is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,

Velma Noble

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510C)

Enclosure: Stamped Label & Technical Bulletin

7510C:T.Lantz:3/1/04:75497-2a

CONCURRENCES								
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WITH COMMENTS ACCEPTED

in EPA Letter Dated: 3 2004

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Fungicide, and Rodenticide Act as registered under EPA Reg. No. Under the Federal Insecticide, amended, for the pesticide,

95.0%

3-(trihydroxysilyl) propyldimethyloctadecyl ammonium chloride....

A Silicone Quaternary Ammonium Salt MICROBIOSTATIC AGENT BIOSHIELD® AM 500 I

(For Manufacturing Use Only)

100.0%

INGREDIENTS: TOTAL

Other Ingredients: Active Ingredient:

WARNING

KEEP OUT OF REACH OF CHILDREN

EPA EST. xxxxx-Ga-xxxx

EPA Reg. No. 75497-2

Lot No.

NET CONTENTS: 2, 4, 8, 16, 20, 22, or 36 flüid oz.; 1, 5, 55, 150, or 300 gal.

FIRST AID

Have the product container or label with you when calling the poison control center or doctor, or going for treatment.

F IN EYES:

Hold eye open and rinse slowly and gently with water for 15-20 minutes.

Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.

Call poison control center or doctor for treatment advice.

IF INHALED:

Move person to fresh air.

If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.

Call a poison control center or doctor for further treatment advice.

F ON SKIN:

Take off contaminated clothing.

Rings skin immediately with plenty of water for 15-20 minutes.

Cail a poison control center or doctor for treatment advice.

SWALLOWED:

Call a poison control center or doctor immediately for treatment advice.

Have person sip a glass of water if able to swallow.

Do not induce vomiting unless told to do so by a poison control center or doctor.

Do not give anything by mouth to an unconscious person.

A microbiostatic agent is an agent that inhibits the growth of odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae. This product does not protect users or others against food-borne or disease-causing bacteria. WARNING. Causes substantial but temporary eye injury. Harmful if absorbed through skin or inhaled. Do not get in eyes. Avoid contact with skin and avoid breathing vapor. Wear protective eyewear (goggles or face shield). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or Regional Office of the EPA. De-activation may be required during clean up if a spill occurs. De-activation of AM 500l can be achieved by the addition of anionic surfactant (such as soap, sulfonates, sulfates) in quantity equivalent to that of AM 5001.

DIRECTIONS FOR USE

is a violation of Federal law to use this product in a manner inconsistent with its labeling

AM500I can be incorporated directly into formulations used to make the end products listed under "Approved Best Pried" of MAEMTS

For formulating use into end use products.

in E.PA Letter Dated:

3 2004 LIMB

Under the Federal Insecricide, Approved Uses

Fungicide, and Proceed Amsocy
AM500 I is approved for use in formulating microbiostats for use in laundry additives, carpet treatment products registered us registered us

pery treatment products. Air filters for furnaces, air-conditioners, air purification devices, automobiles, recirculating air handling systems 75497-2

Air filters/materials

Approved Uses

- Aquarium filter material
- Bed sheats, Dankets, and bedspreads
 - Buffer pads (abrasive and polishing)
- Carpets and draperies.
- Exterior walls (such as stone, concrete, brick)
- Fiberfill for upholstery; sleeping bags, apparel, where the fiber is cotton, natural down, nylon, polyester, rayon, or wool
 - Fiberglass ductboard
 - Fire hose fabric
- Humidifier belts
- Mattress pads and ticking
- Mens underwear and outerwear

- Non-woven disposable diapers
 - Non-woven polyester
- Outerwear apparel (jackets, sweaters, sweatshirts, coats, raincoats, overcoats, jerseys, ponchos)
 - Disposable polyurethane foam cushions for Lapidus Airfloat Systems;
- and coatings include : latex indoor/outdoor paints and stains, woodstains, architectural paints, laquer and maintenance coatings, AM500I can be used in paints and coatings as an in can presertive for protection of paint film and coating film. Types of paints polyester coatings, gel coatings, amino resins, resins used as additive mixes for cement, epoxy laminating resins, and blends coatings, architural coatings and overlays, anti-corrosion coatings, fire-resistant coatings, aliphatic coatings, vinylester and films, laminates and finishes including alkyd, urethane, enamel, epoxy, siloxaline , amino resins, textile coatings, extrusion and copolymers thereof;
- Polyurethane and cellulose foam for household, industrial, and institutional sponges and mops
- Polyurethane and polyethylene foam, when covered
- Polyurethane foam for packaging and cushioning in non-food contact applications
 - Polyurethane foam used as a growth medium for non-food crops and plants
- Pre-moistened towelettes and tissue wipes (these do not impart pesticidal properties)
- Roofing materials defined as shingles, roofing granules, wood shakes, felt, stone and synthetic overcoats
 - Sand bags, tents, tarpaulins, sails, and ropes
 - Athletic and casual shoes
- Shoe insoles
- Shower curtains
- Socks comprised of nylon, nylon/orlon, cotton/nylon, linen/Lycra, acrylic/polypropylene/nylon/Lycra, wool/silk/nylon/Lycra and wool/acrylic/nylon/Lycra
- Throw rugs
- Toweling made of 100 percent cotton, 100 percent polyester, and blends of the two fibers
- Toilet tank and seat covers
- Umbrellas
- Upholstery made of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polyolefins, polypropylene, rayon, spandex, vinyl, wool
- Vacuum cleaner bags and filters
- Vinyl paper-wallpaper for non-food contact surfaces
- Disposable wiping cloths that can be used for multiple purposes such as dusting or washing furniture, cars, walls, windows, floors, appliances, dishes, counter tops; the wiping cloths do not impart pesticide properties
 - Women's hosiery
- Wo៉ូរស្វ៉ូenូវ៉េឡ៉ាnti្ន្រាំate apparel

with CONTRED in EPA Letter Dated:

MAR 3 2004

Under the Federal Insecticide, amended, for the positicide, as registered under EPA Reg. No.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal

Pesticide Storage: Store in original, tightly closed containers below 30°C (86°F) and above 0°C (32°F) in a secure area inaccessible to children and away from food or feed

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. [For homeowner use Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary statement will read: "Container Disposal: Securely wrap original container in several layers of newspaper and discard in trash."]

MSDS CAN BE OBTAINED BY WRITING Nova BioGenetics Inc. 8601 Dunwoody Place, Suite 338, Atlanta, Georgia 30350 or obtain from our FOR MORE INFORMATION CONCERNING THIS PRODUCT, PLEASE CONSULT THE MATERIAL SAFETY DATA SHEET (MSDS). THE website www.novabiogenetics.com

IMPORTANT: WARRANTY AND DISCLAIMER INFORMATION

when used in accordance with directions under normal conditions of use; but this warranty of fitness for a particular purpose does not extend to the use of this product contrary to bulletin instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to the seller, and Nova BioGenetics Inc., warrants that the product conforms to its chemical description and is reasonably fit for the purposes stated in this bulletin buyer assumes the risk of any such use.

Nova SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING THE WARRANTY OF MERCHANTABILITY

in EPA Leffer De WILL CONTIN (ESIR 3 2004

Pungicide, and Rodenticide Act as Under the Federal Insecticido, amended, for the pesticide, **Fegistered** under EPA Reg. No.



Collateral Labeling

NovaBioGenetics Inc. 8601 Dunwoody Place, Suite 338 Atlanta, GA 30350

Information About

Microbiostatic Agents

AM500 I- FOR MANFACTURING USE ONLY

U.S. Environmental Protection Agency Registration Number.......75497-2

Formulating microbiocides for use in laundry additives, Carpet treatment products, upholstery and

Drapery treatment products to give a

Bacteriostastic, fungistatic, mildewstatic activity

TYPICAL PROPERFIES

These values are not intended for use in preparing specifications

Specification Writers: Please contact NovaBioGenetics for information regarding specifications Thermal Stability Water, ethanol, and methanol Z-19487 Proportions with Solubility....... Appearance Colorless liquid inder EPA Reg. No. to the pesticide, Concentration.....5.0% chile, and Rodenticide Act as The Pederal Insection, CH³ MIZ & SIDE Structure....[(CH₃O)₃Si(CH₂O)₃Si(CH₂O)₃H₃₇]+CIin EPA Lefter Dated: WITH COMMENTS **FCCEPTED** CH³

DESCRÉBLION

AM500 I is NovaBioGenetics field's designation for 3-(trimethoxysilyl) propyloctdimethyl ammonium chloride containing 5 percent active ingredient by weight. Alkoxysilanes of this nature have been shown to form durable bonded coatings to a number of materials (see "References" section).

AM500 I offerusers the following features:

- Good durability AOVABIOGENETICS AM500 I imparts biostatic activity to the surface of a wide variety of substrates
- Increased efficiency-through proper application, durable bacteriostatic, fungi static and algistatic surfaces can be-strained with a minimum amount of AM500I.

BENELILZ

The following benefits are derived when a formulation containing the active ingredient is applied to a surface:

- Provides freshness and combats deteration caused by bacteria, fungi, and algae.
- Inhibits growth of bacteria and mildew on the treated article.
- Prolongs the life of an article by inhibiting the growth of bacteria and mildew.
- Resists development of bacterial and fungal odors.
- Retains freshness by resisting the growth of odor-causing bacteria growth and imparts odor resistance.
 Product performance with little degradation up to 375 F

Materials treated with formulations containing the microbiostatics agent AM500 I are preserved by the bacteriostatic, fungistatic and algistatic action imparted by the active ingredient. AM500 I inhibit the growth of microorganisms that are responsible for causing odor, discoloration, and deteration. It also provides residual inhibition of microorganisms to aid in the control of these deleterious effects. AM500 I

forms a coating on a wide variety of substrates and microbiostatic action is exhibited on contact.

ACCEPTED in EPA Letter Dated:

Under the Federal Insecticide,
Immircide, and Rodenticide, Act as
amended, for the pesticide,
registered under EPA Reg. No.

VPPROVED USES

AM500 I is approved for use in formulating microbiostats for use in laundry additives, carpet treatment products, upholstery and drapery treatment products.

The active ingredient in AM500 I is an effective agent against fungi (including mold and mildew) and algae

as a static agent.

AM500 I can be used for incorporation into and treatment of the following items or substrates to impart

bacteriostatic/fungistatic activity.

- Air filters for furnaces, air-conditioners, air purification devices, automobiles, recirculation air handling systems;
- Air filters/materials;
- Aquarium filter materials;
- Bed speets, blankets, and bedspreads;
- Buffer pads(abrasive and polishing);
- Carpets and draperies;

- Figherfil led for upholstery, sleeping bags, apparel, etc., where the fiber is cotton, natural down, nylon,
- polyester, rayon, or wool;
- Fire here fabric;
- Fiberglass duct board;
- Humidifier belts;
- Mattress pads and licking;
- Men's underwear and outerwear;
- Non-woven disposable diapers;
- Non-weven pelyester;
- - Outerwear apparel;
- Disposable polyurethane foam cushions for Lapidus Air float Systems;
- Polytretizane foam for household, industrial, and instructional sponges and mops;
- Polyurethane and polyethylene foam, when covered;
- Polyurethane foam for packaging and cushioning in non-food contact applications;
- Pre-moistened towelettes and tissue wipes (these do not impart pestical properties); Polyurethane foam used as a growth medium for non-food crops and plants;
- Roofing materials- defied as shingles, roofing granules, wood shakes, felt, stone and synthetic overcoats;
- Sandbags, tents, tarpaulins, sails, and ropes;
- Athletic and casual shoes;
- Shoe insoles;
- Shower curtains;
- Lycra, wool/silk/nylon/Lycra and wool/acrylic/nylon/Lycra; Socks compromised of nylon, nylon/orlon, cotton/nylon, linen/Lycra, and acrylic/polypropylene/nylon.
- Throw rugs;
- Toweling made of 100 percent cotton, 100 percent polyester, and blends of the two fibers;
- Toilet tank and seat covers;
- Umbrellas;
- polypropylene, rayon, spandex, vinyl, and wool; Upholstery made of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polyolefin's,
- Vacuum cleaner bags and filters;
- Vinyl paper-wallpaper for non-food contact surfaces;
- cars, walls, windows, floors, appliances, dishes, counter tops, etc.; the wiping cloths do not impart Disposable wiping cloths that can be used for multiple purposes such as dusting or washing furniture,

\$ 200¢ in EPA Letter Daled: MIT COMMENTS ACCEPTED

- Women's imitate apparel.
- DIKECLIONS LOK USE

Women's hosiery; pesticide properties;

AM500 I can be incorporated directly into formulations used for the pesticide. The products listed in this bulletin.

ECAUTIONARY STATEMENTS

\(\sum_{\circ \text{inder the pesticide}} \) \(\sum_{\circ \te

PRECAUTIONARY STATEMENTS

eyewear (goggles or face shield). Wash thoroughly with soap and water after handling. Remove contained get in eyes or clothing. Avoid contact with skin or clothing and avoid breathing vapor. Wear protective

clothing and wash clothing before reuse.

ENNIKONWENLYT HYZYKD?

estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds,

Diselogue Elimation System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

Inactivation of solutions containing AM500 I may be accomplished by one of the following methods:

- Addition of an anionic surfactant or detergent in quantity equivalent to that of AMS00 I in solution;
- Addition of Triton X-100 nonionic detergent at a final concentration of 10,000 ppm (1.0 percent volume/volume) or greater to bath solutions up to 1.0 percent volume/volume of AM500 I.

Every erfort'should be made to contain accidental spills of AM500 I to the immediate area. This may be accomplished by the use of sandbags to confine the spill to facilitate cleanup and disposal. Contaminated sand may then be disposed of by burial in an approved landfill. Many spills may be cleaned up with rags by wiping and/or moping and allowing the liquid to absorb into the fabric. The rags may then be disposed of by incineration.

Floor drains in areas of material use should be protected with sandbags to contain accidental spills.

SLOYVEE VND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in original, unopened containers below 3 C (86 F) and above 0 C (32 F). AM500 I have minimum shelf life of 12 months from the date of shipment from NovaBioGenetics

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an

approved waste disposal facility.

ACCEPTED / with COMMENTS in EPA Letter Dated;

1002 & RAM

Container Disposal: [plastic] Triple ringe (or equivalent). Then offer for recycling or recondition, or puncture and dispose of in a sanifary landfully or procedures (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfull, or by other procedures approved by state and local authorities.

horities. 75497-2

IMPORTANT: WARRANTY AND DISCLAIMER INFORMATION

Before handling, read product label in its entirety

Nova Biogenetics Technologies, Inc., warrants that the product conforms to its chemical description and is reasonably fit for the purposes stated in this bulletin when used in accordance with directions under normal conditions of use; but this warranty of fitness for a particular purpose does not extend to the use of this product contrary to bulletin instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to seller, and buyer assumes the risk of any such use.

MARRANTY, INCLUDING THE WARRANTY OF MERCHANTABILTY.

NOVA BIOGENETICS SPECFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED

KEFRENCES

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- Formation at Silane Coupling Agent Interfaces." J. Compos. Master. 1967,1:278-292. 2. Johannes, O.K., Stark, F.O., Voguel, G.E., and Fleischmann, R.M. "Evidence for Chemical Bond
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- Papers-1978 Nat. Tech. Conf., 1978, 259-261. Getting, R.L. and Triplett, B.L. "A New Durable Antimicrobial Finish for Textiles." AATCC Book of
- 8. Isquith, A.J. and McCallum, C.J., "Surface Kinetic Test Method for Determining Rate of Kill by an
- 9. Malek, J.R. and Speier, J.L. "Development of an Organosilicone Antimicrobial Agent for the Treatment Antimicrobial Solid." Appl. & Environ. Microbial. 1978, 36: 700-704.
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NovaBioGenetics Inc.

Atlanta, GA 30350 8601 Dunwoody Place. Suite 338

ARIDS & SIAM in EPA Letter Dated: MIT COMMENTS ACCEPTED

registered under EPA Reg. No. amended, for the pesticide, Pungicide, and Rodenticide Act as Under the Federal Insecticide,

C-6665L

page 1 8 2

APR 3.0 2008

Elizabeth Brown, Agent for Milliken Chemicals, Inc. c/o ChemReg International, LLC 1990 Old Bridge Road, Suite 201 Lake Ridge, VA 22192-2383

Subject:

Antimicrobial AlphaSan RC 5000 EPA Reg. No. 11631-2 Antimicrobial AlphaSan RC 2000 EPA Reg. No. 11631-3 Antimicrobial AlphaSan RC 7000 EPA Reg. No. 11631-4

Agency Initiated Action-Extension of Time Limited Approval For Certain

Uses

These products currently have time-limited approval until 5/1/03 for all the indirect food, drinking water, and HVAC uses listed on the last stamped labels. The other uses on the labels are not time-limited. This letter represents an Agency initiated action which hereby extends the timelimited approvals for these uses until 5/1/04. This will permit the Agency time to complete the review of the 90-day dog, and two-generation reproduction data you submitted, and to complete the final risk assessment for all uses on the label. The two submitted studies referenced above must be found valid and the final risk assessment of all label uses must be found acceptable.

Failure to find the data valid and the risk assessment acceptable may result in EPA issuing a notice to cancel one or more of the indirect food, drinking water, HVAC or other uses, under FIFRA Section 6(e). This time-limited approval will expire automatically on 5/1/04. Sale or distribution of the subject product bearing labeling for these food contact uses after 5/1/04 will be illegal.

A copy of the applicable label, stamped "Accepted with comments" is attached for your records.

If you have any questions about the comments in this letter, please feel free to contact Tony Kish at 703-308-9443, or myself at 703-308-6341.

> Sincerely, Product Manager Team 33,

Regulatory Management Branch I

CONCURRENCES Intimicrobials Division (7510C) JOHNYZ SURNAME EPA Form 1320-1A (1/90) Printed on Recycled Paper OFFICIAL FILE COPY

65

Antimicrobial AlphaSan® RC 5000

Formulating, Manufacturing, and Fabricating of Treated Article Products Specified in manufacture of plastics, films, fibers, polymeric materials and ceramics. For Use In An antimicrobial additive especially designed to withstand high temperatures in w.o. the Use Directions

Other ingredients Silver sodium hydrogen zirconium phosphate* Active Ingredient

100.0% 0.1% 99.9%

*Contains 3.8% silver, weight/weight

KEEP OUT OF REACH OF CHILDREN CAUTION

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS

contact with skin, eyes, or clothing. Wash thoroughly with soap and water after hendling. Do not breathe dust. Causes moderate eye irritation. Harmful if absorbed through the skin. Avoid

doctor, or going for treatment. Have the product container or label with you when calling a posion control center or

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice

treatment advice. with plenty of water for 15-20 minutes. Call a poison control center or doctor for IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal

covered during storage and away from water and excessive moisture or humidity Pesticide Storage: Do not store in areas accessible to children. Keep containers

site or at an approved waste disposal facility. Pesticide Disposal: Wastes from the use of this product may be disposed of on

by incineration, if allowed by state and local authorities the pesticide is used. Then dispose of empty bag and box in sanitary landfill or Container Disposal: Completely empty bags into processing equipment where

WARRANTY STATEMENT

ACCEPTED

ACCEPTED

ACCEPTED

MILLIKEN CHEMICAL warrants that this product polygon to the chemical description on the label. MILLIKEN CHEMICAL mands he warranties of merchantability or fitness for a particular porposition of the expressed or implied warranty except as stated above

EPA Reg. No. 11631-2

EPA Est. 11631-SC-001 Under the Federal Insection Box 1927 Fungicide, and Rodenticide Attaggurg. S.C. EBOZ 0 8 165W Milliken Chemical 29304

Netropistical and personal reg No amended,

DIRECT HAS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its Inbelling

Autimicrobial AlphaSin/® RC 5000 is an antimicrobial powder

Antimicrobial society to manufactured products. Antimicrobial AlphaSan/® RC 5000 suppresses the growth of bacteria, algae, fungue, mode and mildew, if microbial relivity in the manufactured product could lead to unpleasant odors, dissoloration of deterioration of the product, then such a claim may be made for the manufactured product could lead to unpleasant odors, dissoloration or deterioration of the product, then such a claim may be made for the manufactured product with a product. Manufactured product incorporating Autimicrobial AlphaSan/® RC 5000 may not make any public health claims relating to autimicrobial activity without first containing an EPA registration for the manufactured product which permits such claims. When incorporated into manufactured products, Animicrobial AlphaSan/® RC 500 may not make any public health claims relating to autimicrobial AlphaSan/® RC 500 may not make any public health claims relating to autimicrobial AlphaSan/® RC 500 may not make any public health claims relating to autimicrobial AlphaSan/® RC 500 may not make any public health claims relating to autimicrobial AlphaSan/® RC 500 may not make any public health claims relating to autimicrobial AlphaSan/® RC 500 may not make any public health claims relating to autimicrobial AlphaSan/® RC 500 may not make any public health claims relating to a manufactured product which permits such claims. When incorporated into manufactured products. Animicrobial AlphaSan/® RC 500 may not make any public health claims relating to the manufactured product which permits such claims. does not protect users of any such manufactured product or others against food borne or disease causing bacteria, viruses, germs or other disease causing organisms

uses requiring coating type applications) may contain from 0.1% to 2.0% by weight, except as specifically noted Antimicrobial AlphaSan® RC 5000 may be used in materials that may be incorporated into manufactured products listed below. The final article (or finished coating, for all

FOOD CONTACT USES

Antimicrobial AlphaSan® RC 5000 may be used as an antimicrobial additive in the polymeric manufactured products listed below that are used for manufacturing, packing, packinging, transporting, handling and/or holding food if such use is not intended to have any microbial effect in the food itself. Do sus incorporate Antimicrobial AlphaSain® RC 5000 into any food contact polymer unless that food contact polymer and use conditions are approved and tisted in 21 CFR 174-186 (inclusive), or in the United States Food and Drug Administration's Food Contact Substance Notification System.* Any incorporation of Antimicrobial AlphaSain® RC 5000 into any food contact substance Notification System.* other than an approved and listed food contact polymer is prohibited

bristles; building materials and components; collection and storage equipment (including piping systems, silos, tanks and processing vessels); conveyor belts; cookware; countertops, including kitchen countertops and other countertops; cups; cutting boards; dishes; filters; food and drink containers; food handling equipment; food packaging baltroom hardware, bichen and food processing utensits and supplies; liners; mats; mops; natural and synthetic fibers and fabrics; non-woven fishrics; packaging; paper products (wipes and tissues, towels); plastic fibri; plumbing supplies and fixtures; protective covers; sinks; sponges; tape; tiles; tubing; waste containers. food processing equipment, food storage containers and bags; food trays and covers; food wrap (including coated deli paper, coated ment interfeavers and plastic wrap) gaskets; general purpose containers; glazing for cement tile and for vitreous clains used in plannbing fixtures such as sinks; industrial equipment; insulators; kitchen and Plastics, coatings, films and laminates: Including appliances and equipment; barrier fabrics, beverage dispensing equipment; beverage processing equipment; bottless, brust

Fibers: Including table cloths; napkins; wiping cloths; mops; towels; bags; brush bristles; filters; sponges; packaging (including bags, sacks, wraps, cushion and absorbent materials, containers); conveyor belts; clothing apparel (including uniforms, outerwent, gloves, aproto, conta); kitchen, commercial and industrial wiper and fabrics; food packaging (containers and bags)

Adherives and sealmats fincluding adherives used in the manufacture of wood and plastic composites; adhesives for cenamic tile, wood, paper, circlboard, rubber and plastic grout and joint compound; sealants for pipes; adhesives, sealants and insulating materials for appliances; plumbing adhesives; adhesives for packaging.

DRINKING WATER CONTACT USES

Antimicrobial AlphaSan® RC 5000 may be used for the human drinking water contact uses listed below. The additive may be inconsorated into food bowls and water bowls, dishes, and other containers used by domestic animals. Do not use for any food or drinking water applications involving non-humestic animals.

Plackers, Fibers. Costings, films, and laminates; Adhesives and sealants: Including ice making equipment (water pans, piping, tubing, guards, ice storage bins, ice scoops, buckets, valves, and geskets); drawing water contact materials (water bottles, caps, gaskets, plumbing fixtures, storage tanks, water piping, fithing, valves, spigods, coolers water dispensing components, housing units, and water filter components)

NON-FOOD CONTACT USES

Antimicrobial AlphaSan® RC 5000 may be incorporated into manufactured products listed below for non-food contact uses. Antimicrobial AlphaSan® RC 5000 also may be used for non-food contact uses in any manufactured product listed above for Food Contact Uses or Drinking Water Contact Uses.

synthetic fibers and fabrics; non?woven fabrics; packaging; paper products (wipes and tissues, wall coverings, towels, book covers); plastic film; plumbing supplies and fixtures; protective covers; roofing shingles; shower curtains; siding; sinks; sponges; sports equipment; tape; tiles; tools; tubing; vacuum cleaner bags; wallbuard; walls; walls containers. For coatings used on the inside of fire system springlist gags. Antimicrobial AlphaSan RC 5000 may be incorporated at levels up to 5% by weight. footwear including books; furniture; gaskets; general purpose containers; glazing for cement tile and for vitreous china used in plumbing fixtures such as toilets, Sinks, countertops; indoor and outdoor furniture; industrial equipment; insulation for wire and cable; insulators; kitchen and bathroom hardvare; liners; mats; mops; natural and components; collection and storage equipment (including piping systems, silos, tanks and processing vessels); concrete; conveyor bells; connectors; floor covering; flooring Plastics, coatings, films and laminates, including appliances and equipment; automotive and vehicular parts; barrier fabrics; brush ha sites; building materials and

Fibers: including Mattest cover pack and filling; pith to every blooked; blooked; fiberfill for quilts and pithous; curtaints; draperies: carpet and carpet underlay; rugs; upholstery; table cloths; napkins; wiping cloths; more; towals; logs; wall covering fabrics; cushion pads; sleeping logs; brush bristles; fillers; sponges; packaging; conveyor belts; automotive and misk upholstery; carpering; rear feeks; trust filters; on mittel logs and interior liners; under las; outerwear, uniforms; coats; aprons; sportswear; belts; automotive and misk upholstery; carpering; rear feeks; trust filters; on miske las; outerwear, uniforms; coats; aprons; sportswear; other outdoor equipment, tarps, awnings skepwear, stockings; socks, hosiery; caps; undergarments; inner liners for jackets; shoes; gloves and belinets; artificial leather; book covers; clots for sails, ropes; tents and

Adhesives and sealants: Including adhesives used in the manufacture of wood and plastic composites, adhesives for certainte like, word, paper, cardisoard, nubber and plastic glazing for windows; grout, scalants for papers adhesives; stabilities and insulating material bifor appliances, baltinooms, showers, kitch us, and construction; plumbing adhesives, adhesives for packaging.

Miscellaneous Manufactured Products: Toilets; sinks; tile; flooring; sinceo; plaster; cat filter, drainage and sewerage pipe

Heating, Vemilation and Air Conditioning (HVAC): equipment and related materials including air handlers, plenunts, colls, fins, ize ulation, rigid or flexible ducts, drain pure, their support mechanisms, diffusers, their exchangers, air purifiers, supplemental articles used in the assembly of HVAC systems such as gaskets, fixtures, scalarits, authorizes, and HVAC reinforcing as well as parts and components thereof. These articles could be constructed of fibrous runterials flexibles), non-woven, photic, or costed ratiol-students

d00-345-0372 (8:00 a.m. to 5:00 p.m., Eastern lime)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

December 11, 2003

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

KIMBERLY CASPERSON/TIMOTHY C. MOSES NOVA BIOGENETICS, INC. 8601 DUNWOODY PLACE, SUITE 338 ATLANTA, GA 30350

PRODUCT NAME: BIOSHIELD AM 500 I

COMPANY NAME: NOVA BIOGENETICS, INC.

EPA FILE SYMBOL: 75497-2 EPA RECEIPT DATE: 12/09/03

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Antimicrobials Division, Risk Management Team 31, at (703) 308-6233.

Sincerely,

Fatheria & Thorse Front End Processing Staff

Information Services Branch

Information Resources and Services Division



December 2, 2003

U.S. Environmental Protection Agency OPP Document Processing 7504C, AD, Ariel Rios Building 1200 Pennsylvania Ave., NW Washington, D.C. 20460

SUBJECT: BioShield AM500 I

EPA Registration No. 75497-2

Label Ingredient Statement Amendment

Dear Sir/Madame:

Per a letter from your Antimicrobials Division (7510C - PM #31) dated September 3, 2003, we have changed the ingredient statement on the above referenced product from Otadecylaminodimethyl<u>trimethoxysilyl</u> to Octadecylaminodimethyl<u>trihydroxysilyl</u> propyl ammonium chloride as the active ingredient on our label. The amended BioShield AM500 I Master Label is enclosed.

Please call Tim Moses or me at 770-650-6508 should you have any questions.

Sincerely,

Kimberly Casperson General Manager

Nova BioGenetics Inc.

SEPA Environmental Pr				Registration Amendment Other		OPP Identifier Number 75497
Ар	plicatio	n for Pesticide - Sec	tion	1		
Company/Product Number Nova BioGenetics Inc.		2. EPA Product Ma Velma Noble	nager		3. P	roposed Classification None Restricted
4. Company/Product (Name) BioShield AM500 I 75497-2		PM# 31			-	
5. Name and Address of Applicant (Include ZIP Code) 8601 Dunwoody Pl., Ste. 338 Atlanta, GA 30350 Check if this is a new address			is sim 7549	ilar or identica 97-2	al in co	n FIFRA Section 3(c)(3) composition and labeling
Greek it dies is a new address		Section - II				
Explanation: Use additional page(s) if necessary. (I Per request by the EPA, we have amended our ingredier Octadecylaminodimethyltrihydroxysilyl ammonium chlorid	nt statemen	t on the Master Label for BioSh			ecylamii	nodimethyltrimethoxysilyl to
		Section - III				
Material This Product Will Be Packaged In:						
Child-Resistant Packaging Yes No No If "Yes" N		Water Soluble Packaging Yes ✓ No			Metal Plastic Glass Paper	
	o. per ontainer	If "Yes" No. per Package wgt contain	er			Specify)
	Size(s) Ret	all Container N/A	5. Lo	Labels on		
6. Manner in Which Label is Affixed to Product	Lithogr Paper Stencil	raph Oth	er		-	
		Section - IV				
1. Contact Point Complete items directly below for id	lentification	n of individual to be contacted	, if nec	essary, to proc	ess this	s application.)
Name Timothy C. Moses		Title President, Antimicrobials &	Biocide	- 14 J	70-650	ne Ne. (Include Area Code)
I certify that the statements I have made on this I acknowledge that any knowlingly false or misl both under applicable law.		all attachments thereto are tru		imprisonment o		6. Date Application Received (Stamped)
2. Signeture		3, Title President, Antimicrobials & Bio	cides D			:.::·

5. Date

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete.

4. Typed Name

Timothy C. Moses

White - EPA File Copy (original)

Yellow - Applicant Copy

SEP 3 - 2003

Ms. Jodi Martin Nova Biogenetics, Inc. 8601 Dunwoody Place, Suite 338 Atlanta, GA 30350

SUBJECT:

BioShield AM 500

EPA Registration No: 75497-1

BioShield AM 500 I

EPA Registration No: 75497-2

BST Protectant Concentrate C15 EPA Registration No: 75497-3

BST Protectant RTU 50 EPA Registration No: 75497-4

BST Protectant RTU 75 EPA Registration No: 75497-5

AM 3651PI

EPA Registration No: 75497-7

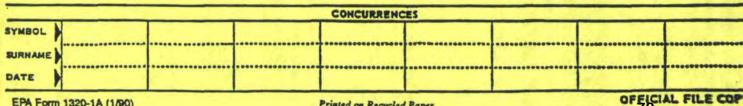
AM 3651P

EPA Registration No: 75497-8

Dear Ms. Martin:

It has come to our attention that the ingredients statement on the label of the above referenced products are incorrect. When Otadecylaminodimethyltrimethoxysilyl propyl ammonium chloride is added to water a reaction occurs resulting in Octadecylaminodimethyltrihydroxysilyl propyl ammonium chloride as the active ingredient.

Your last approved labels for each of these products identified the active ingredient in as 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride.



EPA Form 1320-1A (1/90)

Printed on Recycled Paper

At your next label amendment, submit revised labeling to the Agency which indicates the correct active ingredient name for this product as Octadecylaminodimethyl<u>trihydroxy</u>silyl propyl ammonium chloride.

Should you have any questions concerning this letter and the labeling comments please contact Tracy Lantz at (703) 308-6415.

Sincerely,

Velma Noble

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510C)

7510C:T.Lantz:8/26/03 correct name of AI 107401 products #3

NOTE TO THE JACKET

75497-1, -2, -3, -4, -5, -7, -8

8/26/03

Once the active ingredient name has been corrected for this product, the correct PC code must be assigned. This PC code should be in agreement with 48737-1.

Tracy Lantz

Team 31

BioShield Technologies, Inc.

4

4405 International Boulevard, Suite B109 Norcross, GA 30093

BioShield AM 500 I

MICROBIOSTATIC AGENT & PROTECTANT

A Silicone Quaternary Ammonium Salt (For Manufacturing Use Only)

inert ingredients: Active Ingredient: INGREDIENTS: 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride..... 100.0% 95.0% 5.0%

KEEP OUT OF REACH OF CHILDREN WARNING

EPA Reg. No. xxxx-xx

EPA EST. xxxx-GA-xx

NET CONTENTS: 2, 4, 8, 16, 20, 22, or 36 fluid oz.; 0.5, 1, 5, 55, 150, or 300 gal

STATEMENT OF PRACTICAL TREATMENT

attention. IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

water. Avoid alcohol person. Urink promptly a large quantity of milk, eggwhites, gelatin solution, or, if these are not available, drink large quantities of IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious

with COMMENTS in EPA Letter Dated

registered under EPA Reg. No. amended, for the pesticide, Fangicide, and Rodenticide Act as Under the Federal Insecticide,

70871-2

51 104

in deramin



WASHINGTON, D.C. 20460

May 7, 2003

Mr. Timothy C. Moses
President and CEO
Nova BioGenetics, Inc.
8383 Dunwoody Place, Bldg #3, Box 21
Atlanta, GA 30350

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Dear Mr. Moses:

Subject: Transfer of Pesticide Registrations From

Company Number 70871 to Company Number 75497

Pursuant to your request in your letter and transfer agreement of January 31, 2003, we have approved the transfer of the following registrations from BioShield Technologies, Inc., company number 70871, to Nova BioGenetics, Inc., company number 75497.

The effective date of these changes is the date of this letter.

Registered Products	Old EPA Req. No.	New EPA Reg. No.
BioShield AM 500	70871-1	75497-1
BioShield AM 500 I	70871-2	75497-2
BST Protectant Concentrate C15	70871-3	75497-3
BST Protectant RTU 50	70871-4	75497-4
BST Protectant RTU 75	70871-5	75497-5
BioShield BSTI 1860	70871-12	75497-6
AM 3651PI	70871-13	75497-7
AM 3651P	70871-15	75497-8

You should indicate the new company designation, new EPA Registration Number and new Establishment Number (if it has changed) on the labeling at the next printing which should occur no later than 18 months after the effective date of this transfer. After 18 months, any product released for shipment must bear the new Registration Number and Establishment Number. If you intend to use the labels which currently appear on the transferor's product after the effective date of the transfer,

but within the 18 month grace period, you must maintain complete and accurate records which identify by batch number, lot number, or other suitable description the quantities of such product bearing the transferor's label. Each container or package bearing the transferor's label which is released after the effective date of product registration transfer, must be clearly and accurately marked with the batch number, lot number or other descriptive designation used to identify the product in your records.

Supplemental distribution agreements of registered products do not transfer with the Section 3 registration. It is your responsibility as the registrant to notify any and all supplemental distributors of the transferred product(s) of this transfer agreement. If you wish to enter into supplemental distribution agreements of your product(s) under this new registration, the form "Notice of Supplemental Distribution of a Registered Pesticide Product," EPA Form 8570-5, must be submitted to the Agency for each supplemental distributorship.

You are required to contact your local EPA Regional Office to determine what effect this transfer of pesticide registrations has on the pesticide production establishment registration.

It will not be necessary to submit labeling for review if the only changes are in the company designation and the EPA Registration Number. Other changes in the product and/or labeling may require EPA review and approval prior to initiation. In any correspondence on these products always refer to the U.S. EPA Registration Number listed above.

The transferred registration will have the same status under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 USC 136 et seq., as it had prior to the approval of this transfer.

When registrations are transferred from one company to a second company, all restrictions, data requirements, conditions (suspensions), and deadlines existing on the registrations are transferred with the registrations. The new company is responsible for adhering to or complying with all such restrictions, etc. on the acquired products.

In regard to deadlines, the transferee company is responsible for submitting all required data according to the schedules already established for the acquired products. Failure to do so will result in the issuance of a Notice of Intent to Suspend. Requests from transferee companies for additional time

DIUDHICLD

Environmental Protection Agency Office of Pertialde Programs (7505C) Weekington, DC 20480

285316 2062

110 161 1000 1117 11

Notice of Supplemental Distribution of a Registered Pesticide Product

Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have

EPA Registration Number of Product	Distributor Company Number
970871-26	4875
Note: Do not submi	t distributor product labels
Nome of Registered Product (basic product name accepted by EPA) A M 500	INDCO Pro Active Wiero States
Name and Addres' INDCO Inc.	
N. Railroad & Essex St.	****
P.O. Box 109	
Gloucester City, NJ 08030	: *
Gloucester City, NJ 00050	
Read All Conditions	Before Signing

	same claims as the basic product, provided, however, that r changes to the label are necessary.
specific claims may be deleted if by doing so, no other. The product must remain in the manufacturer's unbroom. The label must bear the EPA registration number of the company number. Distributor product labels must bear the name and addron", "distributed by"; or "sold by" to show that All conditions of the basic registration apply equally to	r changes to the label are necessary. ken container. e basic product, followed by a hyphen and the distributor's tress of the distributor qualified by such terms as "packed
specific claims may be deleted if by doing so, no other. The product must remain in the manufacturer's unbross. The label must bear the EPA registration number of the company number. Distributor product labels must bear the name and add for", "distributed by"; or "sold by" to show that all conditions of the basic registration apply equally to registrant to see that all distributor labeling is kept in a Distributor.	r changes to the label are necessary. ken container. e basic product, followed by a hyphen and the distributor's fress of the distributor qualified by such terms as "packed the name is not that of the manufacturer. distributor products. It is the responsibility of the basic compliance with requirements placed on the basic product.
specific claims may be deleted if by doing so, no other. The product must remain in the manufacturer's unbross. The label must bear the EPA registration number of the company number. Distributor product labels must bear the name and addron", "distributed by"; or "sold by" to show that all conditions of the basic registration apply equally to registrant to see that all distributor labeling is kept in conditions. Distributor market our product under the Distributor Product Name as	r changes to the label are necessary. ken container. be basic product, followed by a hyphen and the distributor's tress of the distributor qualified by such terms as "packed the name is not that of the manufacturer. distributor products. It is the responsibility of the basic compliance with requirements placed on the basic product. butor extiled above, subject to the conditions specified on this Notice.
specific claims may be deleted if by doing so, no other. The product must remain in the manufacturer's unbrown. The label must bear the EPA registration number of the company number. Distributor product labels must bear the name and addron", "distributed by"; or "sold by" to show that for", "distributed by"; or "sold by" to show that all conditions of the basic registration apply equally to registrant to see that all distributor labeling is kept in conditions of the basic registration apply equally to registrant to see that all distributor labeling is kept in conditions of the basic registration apply equally to registrant to see that all distributor labeling is kept in conditions.	r changes to the label are necessary. ken container. e basic product, followed by a hyphen and the distributor's tress of the distributor qualified by such terms as "packed the name is not that of the manufacturer. distributor products. It is the responsibility of the basic compliance with requirements placed on the basic product. butor settled above, subject to the conditions specified on this Notice. Deta
specific claims may be deleted if by doing so, no other. The product must remain in the manufacturer's unbrown. The label must bear the EPA registration number of the company number. Distributor product labels must bear the name and addron", "distributed by"; or "sold by" to show that all conditions of the basic registration apply equally to registrant to see that all distributor labeling is kept in conditions. Distributor product under the Distributor Product Name as	r changes to the label are necessary. ken container. be basic product, followed by a hyphen and the distributor's tress of the distributor qualified by such terms as "packed the name is not that of the manufacturer. distributor products. It is the responsibility of the basic compliance with requirements placed on the basic product. butor extiled above, subject to the conditions specified on this Notice.
specific claims may be deleted if by doing so, no other. The product must remain in the manufacturer's unbrown. The label must bear the EPA registration number of the company number. Distributor product labels must bear the name and addror", "distributed by"; or "sold by" to show that for", "distributed by"; or "sold by" to show that registrant to see that all distributor labeling is kept in company to see that all distributor labeling is kept in company. Distributor market our product under the Distributor Product Name as Signature and Tide of Distributor.	r changes to the label are necessary. ken container. e basic product, followed by a hyphen and the distributor's tress of the distributor qualified by such terms as "packed the name is not that of the manufacturer. distributor products. It is the responsibility of the basic compliance with requirements placed on the basic product. butor settled above, subject to the conditions specified on this Notice. Deta
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specific claims may be deleted if by doing so, no other. 4. The product must remain in the manufacturer's unbro in the label must bear the EPA registration number of the company number. 5. Distributor product labels must bear the name and addron", "distributed by"; or "sold by" to show that it conditions of the basic registration apply equally to registrant to see that all distributor labeling is kept in conditions of the distributor labeling is kept in conditions of the distributor for Distributor and Tide of Distributor. Signature and Tide of Distributor. Registrate the distributor named shope may distribute and set the Distributor and set the Distributor may distribute and set the Distributor.	r changes to the label are necessary. ken container. e basic product, followed by a hyphen and the distributor's dress of the distributor qualified by such terms as "packed the name is not that of the manufacturer. I distributor products. It is the responsibility of the basic compliance with requirements placed on the basic product. Butter active above, subject to the conditions specified on this Notice. Data 3 -5 - 0 2

EPA Form #570-5 (Rev. 8-94) Previous editions ere absolute.

White - DA

4.29.2002



WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

I, <u>Velma Noble, Product Manager/Regulatory Management Branch 1</u>, of the Antimicrobials Division, Office of Pesticide Programs, Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency ("EPA"), certify the pesticide product listed below is, of the date of this letter, a registered product under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and that as such, the product may be sold and marketed in the United States of America as authorized and limited by FIFRA. A true and correct copy of the product label approved by EPA is attached to accompany this letter.

Registration of this product with EPA also denotes that the registrant listed below is responsible for ensuring full compliance with all laws of the United States of America, or governing jurisdiction, regarding the sale, storage and/or disposal of the product. Further, the recipient of this letter is on notice that the status of the referenced registration and/or the accompanying label may change subsequent to date of this letter. EPA assumes no responsibility to notify the recipient of this letter of any change in the status of the registration and/or the product label for the product listed below.

EPA has issued registration number for the product listed below to:

BioShield Technologies, Inc. 440 International Boulevard Suite B109 Norcross, Georgia 30093

EPA Registration Number: Reg. # 70871-2

Name of Product AM 500 I



Name and Title

Date

Official Agency Seal

4405 International Boulevard, Suite B109

Norcross, GA 30093

BioShield AM 500 I

MICROBIOSTATIC AGENT & PROTECTANT

A Silicone Quaternary Ammonium Salt (For Manufacturing Use Only)

95.0%	100.0%			
- Limethyloctadecyl ammonium chloride	3-(trimethoxysilyl) P			
	Active Ingredient:	Inert Ingredients:	TOTAL	INGREDIENTS:

EPA EST. xxxxx-GA-xX

KEEP OUT OF REACH OF CHILDREN WARNING

INGREDIENTS:

EPA Reg. No. xxxx-xx Lot No.

NET CONTENTS: 2, 4, 8, 16, 20, 22, or 36 fluid oz.; 0.5, 1, 5, 55, 150, or 300 gal.

STATEMENT OF PRACTICAL TREATMENT

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.

person. Drink promptly a large quantity of milk, eggwhites, gelatin solution, or, if these are not available, drink large quantities of water. Avoid algohot. IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious

in EPA Letter Dated:

Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. Under the Federal Insecticide,

70871-2





PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

clothing. Avoid contact with skin or clothing, and avoid breathing vapor. Wear protective eyewear (goggles or face shield). Wash Warning. Causes substantial but temporary eye injury. Harmful if absorbed through skin or inhaled. Do not get in eyes or on thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

ENVIRONMENTAL HAZARDS

other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or Regional Office of the EPA.

De-activation of AM 500 I can be achieved by the addition of anionic surfactant in quantity equivalent to that of AM 500 I.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

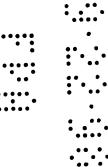
AM 500 I can be incorporated directly into formulations used to make the end products listed under "approved uses."

For formulating use into end-use products.

ACCEPTED with COMMENTS in EPA Letter Dated:

Under the Federal Insecticide, Fangicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.

70871-2



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APPROVED USES

AM 500 I is approved for use in formulating microbiostats for use in laundry additives, carpet treatment products, upholstery and drapery treatment products.

The active ingredient in AM 500 I is effective against fungi (including mold and mildew) and algae as a static agent.

AM 500 I can be used for incorporation into and treatment of the following items or substrates to impart bacteriostatic/fungistatic activity:

- Air filters for furnaces, air-conditioners, air purification devices, automobiles, recirculating air handling systems;
 - Air filters/materials:
- Aquarium filter material:
- Bed sheets, blankets, and bedspreads;
 - Buffer pads (abrasive and polishing);
 - Carpets and draperies;
- Fiberfill for upholstery, sleeping bags, apparel, etc., where the fiber is cotton, natural down, nylon, polyester, rayon, or wool;
 - Fiberglass ductboard;
- Fire hose fabric;
- Humidifier belts;
- Mattress pads and ticking;
- Men's underwear and outerwear;
- - Non-woven disposable diapers;
- Non-woven polyester;
 - Outerwear apparel;
- Disposable polyurethane foam cushions for Lapidus Airfloat Systems;
- Polyurethane foam for household, industrial, and institutional sponges and mops;
 - Polyurethane and polyethylene foam, when covered;
- Polyurethane foam for packaging and cushioning in non-food contact applications; Polyurethane foam used as a growth medium for non-food crops and plants;

Fungicide, and Rodenticide Act as

amended, for the pesticide,

Under the Federal Insecticide,

in EPA Letter Dated: with COMMENTS

ACCEPTED

registered under EPA Reg. No.

70871-2

- Pre-moistened towelettes and tissue wipes (these do not impart pesticidal properties);
- Roofing materials defined as shingles, roofing granules, wood shakes, felt, stone and synthetic overcoats;
 - Sand bags, tents, tarpaulins, sails, and ropes;
- Athletic and casual shoes;
- Shoe insoles;
- Shower ourtains; ...
- Socks comprised of nylon, nylon/orlon, cotton/nylon, linen/Lycra, acrylic/polypropylene/nylon/Lycra, wool/silk/nylon/Lycra and wool/aerylic/nylon/Lycra;
 - Throw rugs;
 - Toweling made of 100 percent cotton, 100 percent polyester, and blends of the two fibers; Toilet tank and seat covers;
 - - Umbrellas;

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- Upitolstery made of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polyolefins, polypropylene, rayon, spandex, vinyl,
 - Vacuum cleaner bags and filters;

- Vinyl paper-wallpaper for non-food contact 3 faces;
- Disposable wiping cloths that can be used for multiple purposes such as dusting or washing furniture, cars, walls, windows, floors, appliances, dishes, counter tops, etc.; the wiping cloths do not impart pesticide properties;
- Women's hosiery; and
- Women's intimate apparel.

EPA REGISTRATION REQUIREMENTS

The applications for which this product is used may require approval by the Environmental Protection Agency on an end-use basis in regard to claims made thereof. Formulators are responsible for satisfying registration requirements for their products.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal

inaccessible to children and away from food or feed. AM 500 I has a minimum shelf life of 12 months from the date of shipment Pesticide Storage: Store in original, tightly closed containers below 30°C (86°F) and above 0°C (32°F) in a secure area

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal

Container Disposal: [Plastic] Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a [Metal] Triple rinse (or equivalent). Then offer for recycling, reconditioning, or puncture and dispose of in a sanitary landfill, or by sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. other procedures approved by state and local authorities.

FOR MORE INFORMATION CONCERNING THIS PRODUCT, PLEASE CONSULT THE MATERIAL SAFETY DATA SHEET (MSDS). THE MSDS CAN BE OBTAINED BY WRITING BIOSHIELD TECHNOLOGIES, INC. AT 4405 INTERNATIONAL with COMMENTS BOULEVARD, SUITE B109, NORCROSS, GEORGIA, 30093

in EPA Letter Dated:

Voct 13 1888

IMPORTANT: WARRANTY AND DISCLAIMER INFORMATION

BioShield Technologies, Inc., warrants that the product conforms to its chemical description and is legisdrem that the product conforms to its chemical description and is the product contrary to build in this build when used in accordance with directions under normal conditions of use; but the product the use of this product contrary to bulletin instructions, or under separation to the use of this product contrary to bulletin instructions, or under the use of this product contrary to bulletin instructions, or under the use of this product contrary to bulletin instructions, or under the use of this product contrary to bulletin instructions. under conditions not reasonably foreseeable to seller, and buyer assumes the risk of any such use. 7087l-2

BIOSHIELD SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING THE WARRANTY OF MERCHANTABILITY



WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

I, <u>Velma Noble, Product Manager/Regulatory Management Branch 1</u>, of the Antimicrobials Division, Office of Pesticide Programs, Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency ("EPA"), certify the pesticide product listed below is, of the date of this letter, a registered product under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and that as such, the product may be sold and marketed in the United States of America as authorized and limited by FIFRA. A true and correct copy of the product label approved by EPA is attached to accompany this letter.

Registration of this product with EPA also denotes that the registrant listed below is responsible for ensuring full compliance with all laws of the United States of America, or governing jurisdiction, regarding the sale, storage and/or disposal of the product. Further, the recipient of this letter is on notice that the status of the referenced registration and/or the accompanying label may change subsequent to date of this letter. EPA assumes no responsibility to notify the recipient of this letter of any change in the status of the registration and/or the product label for the product listed below.

EPA has issued registration number for the product listed below to:

BioShield Technologies, Inc. 440 International Boulevard Suite B109 Norcross, Georgia 30093

EPA Registration Number: Reg. # 70871-2

Name of Product AM 500 I



Name and Title

Date

Official Agency Seal

4405 International Boulevard, Suite B109 Norcross, GA 30093

BioShield AM 500 I

MICROBIOSTATIC AGENT & PROTECTANT

A Silicone Quaternary Ammonium Salt (For Manufacturing Use Only)

Active Ingredient:	3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride
Inert Ingredients:	
TOTAL	
INGREDIENTS:	

5.0% 95.0%

100.0%

KEEP OUT OF REACH OF CHILDREN WARNING

	EPA Reg. No. xxxx-xx
Lot No.	

EPA EST. xxxxx-GA-xx

NET CONTENTS: 2, 4, 8, 16, 20, 22, or 36 fluid oz.; 0.5, 1, 5, 55, 150, or 300 gal.

STATEMENT OF PRACTICAL TREATMENT

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention. attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

person. Drink promptly a large quantity of milk, eggwhites, gelatin solution, or, if these are not available, drink large quantities of water. A voig algohot



ACCEPTED with COMMENTS in EPA Letter Dated:

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.

70871-2



HAZARDS TO HUMANS AND DOMESTIC ANIMALS

clothing. Avoid contact with skin or clothing, and avoid breathing vapor. Wear protective eyewear (goggles or face shield). Wash Warning. Causes substantial but temporary eye injury. Harmful if absorbed through skin or inhaled. Do not get in eyes or on thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

ENVIRONMENTAL HAZARDS

other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or Regional Office of the EPA.

De-activation of AM 500 I can be achieved by the addition of anionic surfactant in quantity equivalent to that of AM 500 I.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

AM 500 I can be incorporated directly into formulations used to make the end products listed under "approved uses."

For formulating use into end-use products.

ACCEPTED with COMMENTS in EPA Letter Dated:

OCT 13 1998

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.

70871-2



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APPROVED USES



AM 500 I is approved for use in formulating microbiostats for use in laundry additives, carpet treatment products, upholstery and drapery treatment products.

The active ingredient in AM 500 I is effective against fungi (including mold and mildew) and algae as a static agent.

AM 500 I can be used for incorporation into and treatment of the following items or substrates to impart bacteriostatic/fungistatic activity;

- Air filters for furnaces, air-conditioners, air purification devices, automobiles, recirculating air handling systems;
 - Air filters/materials;
- Aquarium filter material;
- Bed sheets, blankets, and bedspreads;
- Buffer pads (abrasive and polishing);
 - Carpets and draperies;
- Fiberfill for upholstery, sleeping bags, apparel, etc., where the fiber is cotton, natural down, nylon, polyester, rayon, or wool;
 - Fiberglass ductboard;
- Fire hose fabric;
- Humidifier belts;
- Mattress pads and ticking;
- Men's underwear and outerwear;
 - Non-woven disposable diapers;
- Non-woven polyester;
- Outerwear apparel;
- Disposable polyurethane foam cushions for Lapidus Airfloat Systems;
- Polyurethane foam for household, industrial, and institutional sponges and mops;
 - Polyurethane and polyethylene foam, when covered;
- Polyurethane foam for packaging and cushioning in non-food contact applications; Polyurethane foam used as a growth medium for non-food crops and plants;
- Pre-moistened towelettes and tissue wipes (these do not impart pesticidal properties);
- Roofing materials defined as shingles, roofing granules, wood shakes, felt, stone and synthetic overcoats;

 - Sand bags, tents, tarpaulins, sails, and ropes;
- Athletic and casual shoes;
- Shoe insoles;
- Shower ourtains:••• Socks remprised of nylon, nylon/orlon, cotton/nylon, linen/Lycra, acrylic/polypropylene/nylon/Lycra, wool/silk/nylon/Lycra and wool/aerylic/nylon/Lycra;
- Throw rugs;
- Toweling made of 100 percent cotton, 100 percent polyester, and blends of the two fibers; Toilet tank and seat covers;
 - - Umbrellas:
- Upffolstery made of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polyolefins, polypropylene, rayon, spandex, vinyl, and wool
- Vacuum cleaner bags and filters;

in EPA Letter Dated: with COMMENTS ACCEPTED

Fungicide, and Rodenticide Act as registered under EPA Reg. No. Under the Federal Insecticide, amended, for the pesticide,

70871-2

- - aces: Vinyl paper-wallpaper for non-food contact
- Disposable wiping cloths that can be used for multiple purposes such as dusting or washing fumiture, cars, walls, windows, floors, appliances, dishes, counter tops, etc.; the wiping cloths do not impart pesticide properties;
 - Women's hosiery; and
- Women's intimate apparel.

EPA REGISTRATION REQUIREMENTS

The applications for which this product is used may require approval by the Environmental Protection Agency on an end-use basis in regard to claims made thereof. Formulators are responsible for satisfying registration requirements for their products.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal

inaccessible to children and away from food or feed. AM 500 I has a minimum shelf life of 12 months from the date of shipment Pesticide Storage: Store in original, tightly closed containers below 30°C (86°F) and above 0°C (32°F) in a secure area from BioShield. Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal

Container Disposal: [Plastic] Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a [Metal] Triple rinse (or equivalent). Then offer for recycling, reconditioning, or puncture and dispose of in a sanitary landfill, or by sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. other procedures approved by state and local authorities.

FOR MORE INFORMATION CONCERNING THIS PRODUCT, PLEASE CONSULT THE MATERIAL SAFETY DATA SHEET (MSDS). THE MSDS CAN BE OBTAINED BY WRITING BIOSHIELD TECHNOLOGIES, INC. AT 4405 INTERNATIONAL with COMMENTS

BOULEVARD, SUITE B109, NORCROSS, GEORGIA, 30093

IMPORTANT: WARRANTY AND DISCLAIMER INFORMATION

in EPA Letter Dated: Vocr 1 3 1999

70871-2

BioShield Technologies, Inc., warrants that the product conforms to its chemical description and is legisdressing that the product conforms to its chemical description and is the product for the particular particular purpose does not extend to the use of this product contrary to bulletin instructions, or undersequence to the use of this product contrary to bulletin instructions, or undersequence to the use of this product contrary to bulletin instructions, or undersequence to the use of this product contrary to bulletin instructions, or undersequence to the use of this product contrary to bulletin instructions.

BIOSHIELD SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING THE WARRANTY OF MERCHANTABILITY

under conditions not reasonably foreseeable to seller, and buyer assumes the risk of any such use.

SciReg, Inc. Science and Regulatory Consultants

August 19, 1999

Ms. Velma Noble
Product Manager 31
Antimicrobial Division (7510W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Document Processing Desk
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Re: Certification of registration ("Gold Seals") for AM 500 I (EPA Reg. No. 70871-2)

Dear Velma:

As per your instructions, accompanying this letter is the EPA Form 8570-1 in which BioShield Technologies, Inc. requests the certification of the registration of their manufacturing use product AM 500 I (EPA Reg. No. 70871-2).

Sincerely,

Hale Vandermer, Ph. D. Sr. Regulatory Specialist

Enclosure

Please read instructions	on reverse before complete	ing form.	Form App	roved.	OMB No. 2070-	0060.	Approval ex	cpires 05-31-98
≎EPA	Environmental	nited States Protection Age gton, DC 20460	ency	x	Registration Amendment Other		OPP Identif	ier Number
	Į.	Application for	Pesticide - Sec	tion	1			
1. Company/Product Nur	70871-2		2. EPA Product Mar Velma Nob	nager le			posed Class	-
4. Company/Product (Na	me) AM 500I		PM# 31			X	None	Restricted
BioShield 4405 Inter Norcross,	Applicant <i>Ilnclude ZIP Coo</i> Technologies, national Blvd GA 30093 this is a new address	Inc.	6. Expedited Rev (b)(i), my product to: EPA Reg. No. Product Name	is sim	ilar or identical	in cor	nposition a	
	 	Sec	tion - II			-		
X Amendment - Exp Resubmission in r Notification - Exp	esponse to Agency letter	deted	Final printe Agency let "Me Too" Other - Exp	ter dat Applica	ation.			
We are reque	esting a lette:	r certifying	(Gold Seal	ing) that AM	500) I	·
		Sec	tion - lil			•		
1. Material This Product	Will Be Packaged In:				· · · · · · · · · · · · · · · · · · ·			
Child-Resistant Packagin Yes* No Certification must be submitted	Yes No	No. per If "Ye	Soluble Packaging Yes No s" No. per ge wgt containe	or	J G P	letal lastic lass aper	pecify)	
3. Location of Net Conte	nts Information Container	4. Size(s) Retail Conta	iner	5. Lo	cation of Label E On Label On Labeling			duct
6. Manner in Which Labe	l is Affixed to Product	Lithograph Paper glued Stenciled	Othe	or		•	••••	
			tion - IV			•	••••	
1. Contact Point (Compl	ete items directly below fo	or identification of indi	vidual to be contacted	, if nec	essary, to proce	ss this	epplication.)	<u> </u>
Nama Hale Vand	lermer, Ph.D.	Title Sr	. Regulator	ySpe	ecia lis t	ophon 703	1 a Unclud 494 - 65	e Area Code) 00
	atements I have made on t any knowingly false or m ble law.	isleading statement m	ay be punishable by fi	ne or ii	mprisonment or		Received	
2. Signature	. O.		res., SciRe	g, 1	Inc.(Agen	t)	••••	
4. Typed Name		5. Date				Í		

August 19, 1999

88

James S. Damico

BCT 2 1 1998

BioShield Technologies, Inc. 4405 International Boulevard, Suite B109 Norcross, GA 30093

ATTENTION: Kimberly Lowe

Agent for BioShield

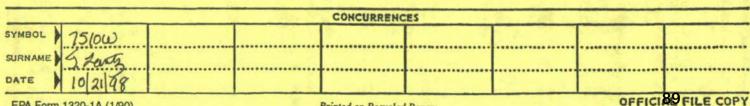
SUBJECT: BioShield AM 500 I

EPA File Symbol 70871-2

Your Registration Dated: October 13, 1998

It has been brought to our attention that the possible intention of the letters "AM" in the name of your product is as an abbreviation for the term "antimicrobial". In our previous correspondences dated September 4, 1998 and October 13, 1998 it was specified that you may not use terms such as "antimicrobial, antibacterial, microbiocide, fungicide, and bactericide" on your label for this product. The purpose of this letter is to inform you that the terms "antimicrobial, antibacterial, microbiocide, fungicide, bactericide" and other similar terms which do not appear on your stamped accepted label may not be used or implied in any of your advertising or literature referencing this product.

We would like to remind you that one of the terms of this registration is as follows "This product has been registered as a microbiostatic agent to formulate products used for materials preservation only; neither this product, nor articles treated with this product, may state or imply any public health claims." The Agency interprets the term "antimicrobial" as implying public health claims.



EPA Form 1320-1A (1/90)

The Agency also strongly suggests that the letters "AM" not be used in the name of this product. We prefer that you submit an Amendment to the Agency to officially change the name of this product so that it's name contains no reference, inferred or implied, to the term "antimicrobial" or any other similar term.

Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,

Velma Noble

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510W)

7510W:T.Lantz:9/1/98:70871-2a

			Reviewer ID	FUPA	LANT	_
			Submission	No. 55	49313	
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					FAPA	
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115 FINAL Response	8		120 Respon	1 1 1	1 3 1998	
75-DAY RESPONSE DUE DAT	E: //(Y) Yes	//(N) NO		3.7	



U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Registration Division (H7505C) 401 "M" St., S.W. Washington, D.C. 20460 EPA Reg. Number:

Date of Issuance:

70871-2

OCT 1 3 1998

NOTICE OF PESTICIDE:

x Registration

Reregistration

(under FIFRA, as amended)

Term of Issuance:

CONDITIONAL

Name of Pesticide Product:

BioShield AM 500 I

Name and Address of Registrant (include ZIP Code):

BioShield Technologies, Inc.

4405 International Boulevard, Suite B 109

Norcross, GA 30093

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

- 1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
- 2. Add the phrase EPA Registration Number "EPA Reg. No. 70871-2".

Signature of Approving Official:

Date:

Velma Noble

Regulatory Management Branch 1
Antimicrobial Division (7510W)

OCT 1 3 1998

EPI	A. Form 8570-6		CONCURRENC	E2		
	7510W					
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DATE	10/9/98				 ***************************************	
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EPA Form 1320-1A (1/90)

page 2 EPA Reg. No. 70871-2

- 3. This product has been registered as a microbiostatic agent to formulate products used for <u>materials preservation only</u>; neither this product, nor articles treated with this product, may state or imply any public health claims.
- 4. Articles or substances treated with this product will be exempt from FIFRA regulation pursuant to 40 CFR 152.25(a) only if the intended use for incorporating this material into the treated article or substance is for protection of the article or substance itself.

The following comments apply to the master label.

- On page one, increase the font size of the signal word "WARNING".
- 2. On page one, revise the phrase "microbiostatic agent & protectant" to read as follows "microbiostatic agent".
- 3. On page two in the "Precautionary Statements" section, increase the font size of the signal word "WARNING" and change the statement which reads "Avoid contact with skin or clothing and avoid breathing vapor." to read as follows "Avoid contact with skin and avoid breathing vapor."

The following comments apply to the collateral label.

- 1. On page one change the statement which begins as follows "As an active ingredient for formulating microbiocides for use..." to read as follows "As an active ingredient for formulating microbiostats for use..."
- 2. On page four in the "Precautionary Statements" section, increase the font size of the signal word "WARNING" and change the statement which reads "Avoid contact with skin or clothing and avoid breathing vapor." to read as follows "Avoid contact with skin and avoid breathing vapor."
- 3. On page four in the "Storage and Disposal" section the Pesticide Storage statement should begin as follows "Store in original, tightly closed containers below 30 C (86 F) and above 0 C (32 F) in a secure area inaccessible to children and away from food or feed. AM 500 I has a minimum..."
- 4. On page four in the "Directions for Use" section include the statement "It is a violation of Federal Law to use this product in a manner inconsistent with its labeling."
- 5. The Agency suggests that your collateral label include a "Statement of Practical Treatment" which is in agreement with the master label.

page 3 EPA Reg. No. 70871-2

Refer to PR Notice 92-5 for Agency requirements regarding the Storage Stability study.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the master label is enclosed for your records. Since the collateral label should remain in agreement with the master label, the Agency will not stamp the collateral label. Submit one (1) copy of the final printed label prior to the release of the product for shipment.

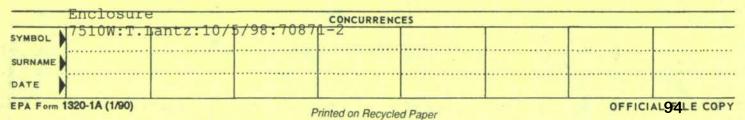
If you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,

Velma Noble

Product Manager 31

Regulatory Management Branch 1 Antimicrobial Division (7510W)



4405 International Boulevard, Suite B109 Norcross, GA 30093

BioShield AM 500 I

MICROBIOSTATIC AGENT & PROTECTANT

A Silicone Quaternary Ammonium Salt (For Manufacturing Use Only)

95.0% 100.0% 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride...... Active Ingredient: Inert Ingredients: INGREDIENTS: TOTAL

KEEP OUT OF REACH OF CHILDREN WARNING

Lot No. _____ EPA Reg. No. xxxx-xx

EPA EST. xxxxx-GA-xx

NET CONTENTS: 2, 4, 8, 16, 20, 22, or 36 fluid oz.; 0.5, 1, 5, 55, 150, or 300 gal.

STATEMENT OF PRACTICAL TREATMENT

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

person. 🏴 in promodija a large quantity of milk, eggwhites, gelatin solution, or, if these are not available, drink large quantities of IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious water. Avoid alcohot

ACCEPTED with COMMENTS in EPA Letter Dated:

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.

70871-2



PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

clothing. Avoid contact with skin or clothing, and avoid breathing vapor. Wear protective eyewear (goggles or face shield). Wash Warning. Causes substantial but temporary eye injury. Harmful if absorbed through skin or inhaled. Do not get in eyes or on thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

ENVIRONMENTAL HAZARDS

other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or Regional Office of the EPA.

De-activation of AM 500 I can be achieved by the addition of anionic surfactant in quantity equivalent to that of AM 500 I.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

AM 500 I can be incorporated directly into formulations used to make the end products listed under "approved uses."

For formulating use into end-use products.

ACCEPTED with COMMENTS in EPA Letter Dated:

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.

70871-2



APPROVED USES

AM 500 I is approved for use in formulating microbiostats for use in laundry additives, carpet treatment products, upholstery and drapery treatment products.

The active ingredient in AM 500 I is effective against fungi (including mold and mildew) and algae as a static agent.

AM 500 I can be used for incorporation into and treatment of the following items or substrates to impart bacteriostatic/fungistatic activity:

- Air filters for furnaces, air-conditioners, air purification devices, automobiles, recirculating air handling systems;
 - Air filters/materials:
- Aquarium filter material;
- Bed sheets, blankets, and bedspreads;
 - Buffer pads (abrasive and polishing)
- Carpets and draperies;
- Fiberfill for upholstery, sleeping bags, apparel, etc., where the fiber is cotton, natural down, nylon, polyester, rayon, or wool;
 - Fiberglass ductboard;
- Fire hose fabric;
- Humidifier belts;
- Mattress pads and ticking;
- Men's underwear and outerwear;
 - Non-woven disposable diapers;
- Non-woven polyester;
- Outerwear apparel;
- Disposable polyurethane foam cushions for Lapidus Airfloat Systems;
- Polyurethane foam for household, industrial, and institutional sponges and mops;
 - Polyurethane and polyethylene foam, when covered;
- Polyurethane foam for packaging and cushioning in non-food contact applications;

Fungicide, and Rodenticide Act as

Under the Federal Insecticide,

in EPA Letter Dated: With COMMENTS

ACCEPTED

registered under EPA Reg. No.

70871-2

amended, for the pesticide,

- Polyurethane foam used as a growth medium for non-food crops and plants;
- Pre-moistened towelettes and tissue wipes (these do not impart pesticidal properties);
- Roofing materials defined as shingles, roofing granules, wood shakes, felt, stone and synthetic overcoats;
 - Sand bags, tents, tarpaulins, sails, and ropes;
- Athletic and casual shoes;
- Shoe insoles;
- Shower ourtains, •
- Socks comprised of nylon, nylon/orlon, cotton/nylon, linen/Lycra, acrylic/polypropylene/nylon/Lycra, wool/silk/nylon/Lycra and wool/aerylic/nylon/lycra;
- Throw rugs;
- Toweling made of 100 percent cotton, 100 percent polyester, and blends of the two fibers; Foilet tank and seat covers;
 - - Umbrellas;
- *Upifolstery*made of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polyolefins, polypropylene, rayon, spandex, vinyl, and wool:
 - Vacuum cleaner bags and filters;

- aces; Vinyl paper-wallpaper for non-food contact 3
- Disposable wiping cloths that can be used for multiple purposes such as dusting or washing fumiture, cars, walls, windows, floors, appliances, dishes, counter tops, etc.; the wiping cloths do not impart pesticide properties;
 - Women's hosiery; and
- Women's intimate apparel.

EPA REGISTRATION REQUIREMENTS

The applications for which this product is used may require approval by the Environmental Protection Agency on an end-use basis in regard to claims made thereof. Formulators are responsible for satisfying registration requirements for their products.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal

inaccessible to children and away from food or feed. AM 500 I has a minimum shelf life of 12 months from the date of shipment Pesticide Storage: Store in original, tightly closed containers below 30°C (86°F) and above 0°C (32°F) in a secure area from BioShield. Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal

Container Disposal: [Plastic] Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a [Metal] Triple rinse (or equivalent). Then offer for recycling, reconditioning, or puncture and dispose of in a sanitary landfill, or by sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. other procedures approved by state and local authorities.

FOR MORE INFORMATION CONCERNING THIS PRODUCT, PLEASE CONSULT THE MATERIAL SAFETY DATA SHEET (MSDS). THE MSDS CAN BE OBTAINED BY WRITING BIOSHIELD TECHNOLOGIES, INC. AT 4405 INTERNATIONAL with COMMENTS BOULEVARD, SUITE B109, NORCROSS, GEORGIA, 30093.

in EPA Letter Dated:

IMPORTANT: WARRANTY AND DISCLAIMER INFORMATION

BioShield Technologies, Inc., warrants that the product conforms to its chemical description and is Resignate the seathes purposes stated in this bulletin when used in accordance with directions under normal conditions of use; but the period of the use of this product contrary to bulletin instructions, or under seather that the use of this product contrary to bulletin instructions, or undersease does not extend to the use of this product contrary to bulletin instructions, or undersease does not extend to the use of this product contrary to bulletin instructions, or undersease does not extend to the use of this product contrary to bulletin instructions, or undersease does not extend to the use of this product contrary to bulletin instructions. V 0CT 1 3 1998 under conditions not reasonably foreseeable to seller, and buyer assumes the risk of any such use. BIOSHIELD SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING THE WARRANTY OF MERCHANTABILITY

COLLATERAL LABELING

BioShield Technologies, Inc.

4405 International Boulevard, Suite B109 Norcross, GA 30093

Information About Microbiostatic Agents

AM 500 I — FOR MANUFACTI	JRING USE ONLY
U.S. Environmental Protection Agency Registration Number	
	Silicone quaternary ammonium salt
	Low-viscosity liquid
Special Properties	Surface bondability
Primary Uses	As an active ingredient for formulating
•	microbiocides for use in laundry additives,
	carpet treatment products, upholstery and
	drapery treatment products to give a
	bacteriostatic, fungistatic, mildewstatic activity

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CH₃
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[(CH ₃ O) ₃ Si(CH ₂) ₃ N–C ₁₈ H ₃₇] ⁺ Cl
l CH₃
5.0%
Colorless liquid
Miscible in all proportions with
water, ethanol, and methanol
Stable to 30°C (86°F)
ation regarding specifications
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DESCRIPTION

AM 500 I is BioShield's designation for 3-(trimethoxysilyI) propyloctadecyldimethyl ammonium chloride containing 5 percent active ingredient by weight. Alkoxysilanes of this nature have been shown to form durable bonded coatings to a number of materials (see "References" section).

AM 500 I offers users the following features:

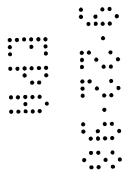
- Good durability—BIOSHIELD AM 500 I imparts biostatic activity to the surface of a wide variety of substrates.
- Increased efficiency—through proper application, durable bacteriostatic, fungistatic and algistatic surfaces can be attained with a minimum amount of AM 500 I.

BENEFITS

The following benefits are derived when a formulation containing the active ingredient is applied to a surface:

- Provides freshness and combats deterioration caused by bacteria, fungi, and algae.
- Inhibits growth of bacteria and mildew on the treated article.
- Prolongs the life of a article by inhibiting the growth of bacteria and mildew.
- Resists development of bacterial and fungal odors.
- Retains freshness by resisting the growth of odor-causing bacteria and mildew (fungus).
- Provides a chemical treatment that enables fabrics to resist odors.
- Provides a unique chemical treatment that resists mildew and bacteria growth and imparts odor resistance.
- Product performance with little degradation up to 375°F.

Materials treated with formulations containing the microbiostatic agent AM 500 I are preserved by the bacteriostatic, fungistatic and algistatic action imparted by the active ingredient. AM 500 I inhibits the growth of microorganisms that are responsible for causing odor, discoloration and deterioration. It also provides residual inhibition of microorganisms to aid in the control of these deleterious effects. AM 500 I forms a coating on a wide variety of substrates and microbiostatic action is exhibited on contact.





APPROVED USES

AM 500 I is approved for use in formulating microbiostats for use in laundry additives, carpet treatment products, upholstery and drapery treatment products.

The active ingredient in AM 500 I is effective against fungi (including mold and mildew) and algae as a static agent.

AM 500 I can be used for incorporation into and treatment of the following items or substrates to impart bacteriostatic/fungistatic activity.

- Air filters for furnaces, air-conditioners, air purification devices, automobiles, recirculating air handling systems;
- Air filters/materials;
- Aguarium filter material;
- · Bed sheets, blankets, and bedspreads;
- Buffer pads (abrasive and polishing);
- · Carpets and draperies;
- Fiberfill for upholstery, sleeping bags, apparel, etc., where the fiber is cotton, natural down, nylon, polyester, rayon, or wool;
- Fiberglass ductboard;
- Fire hose fabric;
- Humidifier belts;
- Mattress pads and ticking;
- Men's underwear and outerwear;
- Non-woven disposable diapers;
- Non-woven polyester;
- Outerwear apparel;
- Disposable polyurethane foam cushions for Lapidus Airfloat Systems;
- Polyurethane foam for household, industrial, and institutional sponges and mops;
- Polyurethane and polyethylene foam, when covered;
- Polyurethane foam for packaging and cushioning in non-food contact applications;
- Polyurethane foam used as a growth medium for non-food crops and plants;
- Pre-moistened towelettes and tissue wipes (these do not impart pesticidal properties);
- Roofing materials defined as shingles, roofing granules, wood shakes, felt, stone and synthetic overcoats:
- Sand bags, tents, tarpaulins, sails, and ropes;
- Athletic and casual shoes;
- · Shoe insoles;
- Shower curtains;
- Socks comprised of nylon, nylon/orlon, cotton/nylon, linen/Lycra, acrylic/polypropylene/nylon/Lycra, wool/silk/nylon/Lycra and wool/acrylic/nylon/Lycra;
- Throw rugs;
- Toweling made of 100 percent cotton, 100 percent polyester, and blends of the two fibers;
- Toilet tank and seat covers;
- Umbrellas:
- Upholstery made of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyettniene, polyolefins polypropylene, rayon, spandex, vinyl, and wool;
- Vacuum cleaner bags and filters;
- Vinyl paper-wallpaper for non-food contact surfaces;
- Disposable wiping cloths that can be used for multiple purposes such as dusting or washing furniture, cars, walls, windows, floors, appliances, dishes, counter tops, etc.; the wiping cloths do not impacte pesticide properties;
- · Women's hosiery; and
- Women's intimate apparel.

DIRECTIONS FOR USE

AM 500 I can be incorporated directly into formulations used to make the end products listed in this bulletin.

PRECAUTIONARY STATEMENTS

Warning. Causes substantial but temporary eye injury. Harmful if absorbed through skin or inhaled. Do not get in eyes or on clothing. Avoid contact with skin or clothing, and avoid breathing vapor. Wear protective eyewear (goggles or face shield). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

Inactivation of solutions containing AM 500 I may be accomplished by one of the following methods:

- addition of an anionic surfactant or detergent in quantity equivalent to that of AM 500 I in solution; or
- addition of Triton X-100 nonionic detergent at a final concentration of 10,000 ppm (1.0 percent volume/volume) or greater to bath solutions up to 1.0 percent volume/volume of AM 500 I.

Every effort should be made to contain accidental spills of AM 500 I to the immediate area. This may be accomplished by the use of sandbags to confine the spill to facilitate cleanup and disposal. Contaminated sand may then be disposed of by burial in an approved landfill. Many spills may be cleaned up with rags by wiping and/or mopping and allowing the liquid to absorb into the fabric. The rags may then be disposed of by incineration.

Floor drains in areas of material use should be protected with sandbags to contain accidental spills.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in original, unopened containers below 3°C (86°F) and above 0°C (32°F). AM 500 I has a minimum shelf life of 12 months from the date of shipment from BioShield.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: [Plastic] Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. [Metal] Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Before handling, read product label in its entirety

IMPORTANT: WARRANTY AND DISCLAIMER INFORMATION

BioShield Technologies, Inc., warrants that the product conforms to its chemical description and is reasonably fit for the purposes stated in this bulletin when used in accordance with directions under normal conditions of use; but this warranty of fitness for a particular purpose does not extend to the use of this product contrary to bulletin instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to seller, and buyer assumes the risk of any such use.

BIOSHIELD SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING THE WARRANTY OF MERCHANTABILITY.

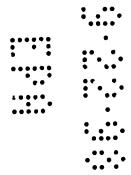
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 Am. Dyestuff Rep., 1983, 6:56-59.
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BioShield Technologies, Inc. 4405 International Boulevard, Suite B109 Norcross, GA 30093





United States Environmental Protection Agency

401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms.

Send comments regarding burden estimate or any other aspect of this co OPPE Information Management Division (2137), U.S. Environmental Pro Do not send the completed form to this address.			
Certification with	Respect to C	itatio	n of Data
Applicant's/Registrant's Name, Address, and Telephone Number BioShield Technologies, Inc. 4405 International Boulevard, Suite B109 Norcross, GA 30093 (770) 925-3432			EPA Registration Number/File Symbol 70871-E
Active Ingredient(s) and/or representative test compound(s)			Date
3-(trimethoxysilyl) propyldimethyloctadecyl ammon	ium chloride		9/21/98
General Use Pattern(s) (list all those claimed for this product using 40 CFR F	Part 158)		Product Name
MUP: indoor non-food; indoor residential			BioShield AM 500 I
Note: If your product is a 100% repackaging of another purchased EPA-regis submit this form. You must submit the Formulator's Exemption Statement (I		for all th	ne same uses on your label, you do not need to
I am using responding to a Data-Call-In-Notice, and have included with should be used for this purpose).	this form a list of con	npanies s	sent offer of compensation (the Data Matrix form
SECTION I: METHOD OF DA	TA SUPPORT	(Chec	ck one method only)
I am using the cite-all method of support, and have included with form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	selective met	hod), and	ve method of support (or cite-all option under the d have included with this form a completed list of e Data Matrix form must be used).
SECTION II: G	0		
[Required if using the cite-all method or when using the cite-all option under	the selective method	to satisfy	y one or more data requirements]
I hereby offer and agree to pay compensation, to other persons, with reg	gard to the approval o	f this app	plication, to the extent required by FIFRA.
SECTION	III: CERTIFICA	NOITA	
I certify that this application for registration, this form for reregistration, and its response. In addition, the form for reregistration, or the Data-Call- In response. In additional supported by all data in the Agency's files that (1) concern the properties of ingredients in this product; and (2) is a type of data that would be required to if the application sought the initial registration of a product of identical or similar to certify that for each exclusive use study cited in support of this regist	tion if the cite-all option or effects of this produ be submitted under to lar composition and u	on under uct or an he data r ises.	the selective method is indicated in Section I, this application identical or substantially similar product, or one or more of the requirements in effect on the date of approval of this application
written permission of the original data submitter to cite that study. I certify that for each study cited in support of this registration or rereg have obtained the permission of the original data submitter to use the study ir study; (d) the study is in the public literature; or (e) I have notified in writing the required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to comment the use of the study.	n support of this appli ne company that sub	cation; (d	c) all periods of eligibility for compensation have expired for the e study and have offered (I) to pay compensation to the extent
I certify that in all instances where an offer of compensation is required sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submit upon request, I understand that the Agency may initiate action to deny, canced a certify that the statements I have made on this form and all attasticates or misleading statement may be punishable by fine or imprisonment.	itted to the Agency up el or suspend the reg chments to it are tr	oon reque istration o	est. Should I fail to produce such evidence to the Agency of my product in conformity with FIFRA. urate and complete • acknowledge that any knowingly
Signature Kimberty Sowe	9/21/98	Kimberl Regulat Jellinek	or Printed Name and Title ly Lowe

EPA Form 8570-34 (9-97) Electronic and Paper Versions available. Submit only Paper version.

401 M Street, S.W.

WASHINGTON, D.C. 20460

response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director: OPPE Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address. Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per

1.			DATA MATDIY			
			VIVIVIVIVIVI			
긔	Date	September 21, 1998		EPA Reg. No./File Symbol 70871-E	=	Page 1 of 2
7	Applicant's/Registrant's Name & Address			Product		
		BioShield Technologies, Inc. 4405 International Boulevard, Suite B 109 Norcross, GA 30093		BioShield AM 500 I		
	Ingredient 3-(trimethoxysi	3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride				
	Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	61-1	Product Identity and Composition	44279401	BioShield Technologies, Inc.	OWN	
	61-2	Description of Beginning Materials and the Manufacturing Process	44279402	BioShield Technologies, Inc.	OWN	
	61-3	Discussion of Formation of Impurities	44279403	BioShield Technologies, Inc.	OWN	
	62-1, 62-2, 62-3	Preliminary Analysis, Certification of Ingredient Limits, and Analytical Method	44351901	BioShield Technologies, Inc.	OWN	
	63-2, 63-3, 63-4, 63-7, 63-12, 63-18	Product Chemistry	44279404	BioShield Technologies, Inc.	OWN	
	63-17, 63-20	Product Chemistry: Storage Stability & Corrosion Characteristics	-			(Being Conducted)
∞ >‱	81 Series	Acute Toxicology	40385201	Aegis Environmental Mgmt, Inc.	ало	
∞ ∕5	81-1	Acute Oral Toxicity	42456511	Aegis Environmental Mgmt, Inc.	PER	
*5	81-2	Acute Dermal Toxicity	43219901	Aegis Environmental Mgmt, Inc.	PER	
106	Signature Gimbers	Sawe		Name and Title Kimberly Lowe, Regulatory Specialist; Jellinek, Schwartz & Connolly, Inc. Authorized Representative of BioShield Technologies, Inc.	atory molly, Inc. ld	Date 9/31/98

EPA Form 8570-35 (9-97) Electronic and Paper Versions Available. Submit only Paper version.

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106

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response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director. OPPE Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per Street, S.W., Washington, DC 20460. Do not send the form to this address.

		Q	DATA MATRIX			
	Date	September 21, 1998		EPA Reg. No./File Symbol 70871-E		Page 2 of 2
	Applicant's/Registrant's Name & Address	8		Product		
		BioShield Technologies, Inc. 4405 International Boulevard, Suite B 109 Norcross, GA 30093		BioShield AM 500 I		
	Ingredient 3-(trimethoxys	3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride				
	Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
3/	81-3	Acute Inhalation Toxicity	41157803, 93218038, 93218014	Aegis Environmental Mgmt, Inc.	PER	
7	81-4	Primary Eye Irritation	44553501	BioShield Technologies, Inc.	OWN	
8	81-5	Primary Dermal Irritation	93218047, 42456513	Aegis Environmental Mgmt, Inc.	PER	
\ \ \	81-6	Dermal Sensitization	42197401	Aegis Environmental Mgmt, Inc.	PER	
10	Signature	•		Name and Title Kimberly Lowe, Regulatory	gulatory	Date
7	Kimber	2 dave		Specialist; Jellinek, Schwartz & Connolly, Inc. Authorized Representative of BioShield Technologies, Inc.	olly, Inc. d	36/10/6

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	D	DATA MATRIX			
Date	September 21, 1998		EPA Reg. No./File Symbol 70	70871-E	Page I of 2
Applicant's/Registrant's Name & Address			Product		
	BioShield Technologies, Inc. 4405 International Boulevard, Suite B 109 Norcross, GA 30093		BioShield AM 500 I		
Ingredient 3-(trimethoxysil	3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			BioShield Technologies, Inc.	OWN	
			BioShield Technologies, Inc.	OWN	
			BioShield Technologies, Inc.	OWN	
			BioShield Technologies, Inc.	OWN	
			BioShield Technologies, Inc.	OWN	
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			Aegis Environmental Mgmt, Inc.	c. OLD	
100 mm			Aegis Environmental Mgmt, Inc.	c. PER	
			Aegis Environmental Mgmt, Inc.	c. PER	
Signature			Name and Title Kimberly Lowe, Regulatory	egulatory	Date
801	; Shur		Specialist, Jellinek, Schwartz & Connolly, Inc. Authorized Representative of BioShield Technologies Inc.	c Connolly, Inc. Shield	36/1c/b
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	D	DATA MATRIX			
Date	September 21, 1998		EPA Reg. No./File Symbol 70871-E	71-E	Page 2 of 2
Applicant's/Registrant's Name & Address	SS		Product		
	BioShield Technologies, Inc. 4405 International Boulevard, Suite B 109 Norcross, GA 30093		BioShield AM 500 I		
Ingredient 3-(trimethoxy	3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Aegis Environmental Mgmt, Inc.	Inc. PER	
			BioShield Technologies, Inc.	OWN	
			Aegis Environmental Mgmt, Inc.	Inc. PER	
			Aegis Environmental Mgmt, Inc.	Inc. PER	
Signature	•		Name and Title Kimberly L	Kimberly Lowe, Regulatory	Date

A Form 8570-35 (9-97) Electronic and Paper Versions Available. Submit only Paper version.

Specialist; Jellinek, Schwartz & Connolly, Inc.

Authorized Representative of BioShield

Technologies, Inc.

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Jellinek, Schwartz & Connolly, Inc.

1525 Wilson Boulevard, Suite 600 Arlington, VA 22209 (703) 527-1670 • Fax (703) 527-5477



AN TO COMPANY

Hand Delivered

September 21, 1998

Ms. Velma Noble (PM 31)
Regulatory Management Branch I
Antimicrobials Division (7510W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

Re: Response to EPA Letter Dated September 4, 1998 BioShield AM 500 I (EPA File Symbol 70871-E)

Dear Ms. Noble:

On behalf of BioShield Technologies, Inc. (BioShield; 4405 International Boulevard, Suite B109, Norcross, Georgia, 30093), we are submitting a response to your September 4, 1998, letter regarding the pending registration of BioShield AM 500 I (EPA File Symbol 70871-E). Enclosed are the following materials:

- an Application for Pesticide Registration form (8570-1, with correct container sizes indicated);
- · a revised Certification with Respect to Citation of Data form;
- a revised data matrix;
- one copy of proposed product labels submitted on May 5, 1998;
- one copy of revised, proposed product labels with revisions highlighted; and
- five copies of revised, proposed product labels.

As we discussed with Dennis Edwards and Tracy Lantz, we are satisfying the requirement for an acute inhalation study (EPA Guideline No. 81-3) by citing three submissions owned by Aegis Environmental Management, Inc., and previously accepted by the Agency (MRID Numbers 411578-03, 932180-14, and 932180-38). The revised data matrix references these three submissions.

We agree with the Agency's interpretation of the requirement for a dermal sensitization study (EPA Guideline No. 81-6) as stated in the January 13, 1998, review of MRID 421974-01. As stated, the Agency believes the study is acceptable until a complete review is conducted in the reregistration process. The revised data matrix references this study.

The toxicity profile for this product is as follows:

Acute Oral Toxicity IV
Acute Dermal Toxicity III
Acute Inhalation Toxicity III
Primary Eye Irritation II
Primary Skin Irritation III
Dermal Sensitization Non-Sensitizer

Thus, the overall toxicity is Category II (based on eye irritation). The revised labeling includes language based on this toxicity information for the "Statement of Practical Treatment" and "Precautionary Statements" sections.

The storage stability and corrosion characteristics studies (EPA Guideline Nos. 63-17 and 63-20) are ongoing at Springborn Laboratories, Inc. (Wareham, MA); BioShield expects to submit a study report later this year.

The terms "antibacterial" and "antimicrobial" have been replaced with "microbiostat" or "microbiostatic" on the proposed label.

As requested in your September 4, 1998, letter, the specific changes made to the proposed BioShield AM 500 I labeling are as follows:

- 1. On page three of the main labeling, the statement "The active ingredient in AM 500 I is effective against fungi (including mold and mildew), algae, and yeasts." has been changed to read as follows: "The active ingredient in AM 500 I is effective against fungi (including mold and mildew) and algae as a static agent."
- 2. On page three of the main labeling, the statement "AM 500 I can be used for incorporation into and treatment of the following items or substrates to impart durable antimicrobial protection:" has been changed to read as follows: "AM 500 I can be used for incorporation into and treatment of the following items or substrates to impart bacteriostatic/fungistatic activity:"
- 3. On page one of the collateral labeling, the statement "Primary Uses....As an active ingredient for fomulating microbiocides for use in laundry additives, carpet treatment products, upholstery and drapery treatment products, and building and cleaning treatment products to give a surface-durable antimicrobial treatment" has been changed to read as follows: "Primary Uses....As an active ingredient for formulating microbiocides for use in laundry additives, carpet treatment products, upholstery and drapery treatment products to give a bacteriostatic, fungistatic, mildewstatic activity."

- 4. On page two of the collateral labeling, the statement "Good durability-BIOSHIELD AM 500 I Antimicrobial Agent imparts durable biostatic activity to the surface of a wide variety of substrates; it is leach-resistant and nonmigrating and is not consumed by microorganisms." Has been changed to read as follows: "Good durability-BIOSHIELD AM 500 I imparts biostatic activity to the surface of a wide variety of substrates."
- 5. On page two of the collateral labeling, the statement "Provides hygienic freshness and combats deterioration caused by bacteria, fungi, algae, and yeasts." has been changed to read as follows: "Provides freshness and combats deterioration caused by bacteria, fungi, and algae."
- 6. On page three of the collateral labeling, the statement "The active ingredient in AM 500 I is effective against fungi (including mold and mildew), algae, and yeasts." has been changed to read as follows: "The active ingredient in AM 500 I is effective against fungi (including mold and mildew) and algae as a static agent."
- 7. On page three of the collateral labeling, the statement "AM 500 I can be used for incorporation into and treatment of the following items or substrates to impart durable antimicrobial protection:" has been changed to read as follows: "AM 500 I can be used for incorporation into and treatment of the following items or substrates to impart bacteriostatic/fungistatic activity:"

As also requested in your September 4, 1998, letter, the additional changes made to the proposed BioShield AM 500 I labeling are as follows:

- A. In the "Directions for Use" section of the main labeling and collateral labeling, the entire statement beginning with "AM 500 I can also be diluted by adding 0.2 to 2 fluid ounces..." and ending with "...to give a final treatment of 0.1 to 1.0 percent by weight active ingredient." has been deleted. Also, the paragraph beginning with "After applying the antimicrobial agent..." and ending with "...should be determined for each application before use." has been deleted.
- B. On the main labeling, the statement "AM 500 I is approved for use in formulating microbiocides for use in laundry additives, carpet treatment products, upholstery and drapery treatment products, and building cleaning and treatment products." has been revised to read as follows: "AM 500 I is approved for use in formulating microbiostats for use in laundry additives, carpet treatment products, upholstery and drapery treatment products." This change has been made to the top of page three of the collateral labeling as well.
- C. The container sizes we propose are as follows: 2, 4, 8, 16, 20, 22, and 36 ounce containers and 0.5, 1, 5, 55, 150, and 300 gallon containers. These sizes are listed on the revised draft labeling as well as on the revised Application for Pesticide form 8570-1.



- D. The "Environmental Hazards" section of the main labeling and collateral labeling has been revised as follows: the sentence "Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark." has been replaced with "This pesticide is toxic to fish."
- E. The "Storage and Disposal" section of the main labeling and collateral labeling has been revised. As per PR Notice 83-3, we propose the following "Pesticide Disposal" language: "Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility." The "Container Disposal" section has been revised as follows: "Plastic Containers: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. Metal Containers: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities."

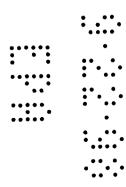
If you have any questions, please contact me at (703) 312-8539. Thank you.

Sincerely,

Kimberly Lowe
Regulatory Specialist
Jellinek, Schwartz & Connolly, Inc.
Authorized Representative of
BioShield Technologies, Inc.

Enclosures

c: Joachim Berkner, BioShield



Please read instructions on reverse before	e completing form.			Form Approve	d. OMB No. 20	70-0060 Approval Expires 5-31-98
	United States			Registration		OPP Identifier Number
EPA Enviro	onmental Protect Washington, DC 20		y	Amendment Other	.	
,	Applicat	ion for Pest	ticide - S	ection I		
Company/Product Number	0871-E		2. EPA Produc	·	3. Pr	oposed Classification
4. Company/Product (Name)			PM#			None Restricted
BioShie 	eld AM 500 I			31		
5. Name and Address of Applicant (Inc. BioShield Technologies, In						FIFRA Section 3 (c) (3)
4405 International Boulevar			to:	duct is similar or identi		_
Norcross, GA 30093			1			
Check if this is a ne	w address		Product Name	e		
		Section	n - II			
Amendment - Explain below.			Final pr	rinted labels in respon	nse to	
Resubmission in response to Ag	ency letter dated <u>Septerr</u>	ber 4, 1998	"Me To	oo" Application.		
Notification - Explain below.	Other -	- Explain below.				
Explanation: Use additional Page	(s) if necessary. (For sec	tion I and Section II)			
Submission of information	and revised labels	in response to	o EPA letter	dated Septemb	er 4, 1998	3 .
		•		-		
		Section	1 - III			
1. Material This Product Will Be Pag						
Child-Resistant Packaging	Unit Packaging Yes		Water Soluble Yes	Packaging	2. Typ	oe of Container etal
Yes*	l ⊠ №		No No		⊠ Pia	
⊠ No	If "Yes"	No. per	If "Yes"	No. Per	1 =	ass per
* Certification must be submitted	Unit Packaging wgt.	Container	Unit Package v	wgt. Container	1	her (Specify)
3. Location of Net Contents Information		ze(s) Retail Contain 8, 16, 20, 22, or 36		5. Location of Labe	el Directions	
Label Container		1, 5, 55, 150, or 300		On Label On Labeling	accompanyi	ng product
6. Manner in Which Label is Affixed to	Product	Lithograph				
	×	Paper glued		Other		
		Stenciled Section) - IV			
1. Contact Point (Complete items dir	rectly below for identification			cessary to process thi	is application	.)
Name Kimberly Lowe		Title Regulator	y Specialist artz & Connolly		ephone No. (03) 312-85	include Area Code)
Killiberry Lowe			presentative of		00, 012-00	••••
I certify that the statements which		fication		ate and complete		6 Date Application Received
I acknowledge that any knowingly both under applicable law.						(Stamped)
2. Signature	4	3. Title		•		• ••
Kimberly &	me	Regulatory Spec Jellinek, Schwar Authorized Repr	tz & Connolly, I	inc. ioShield Technologi	ies, Inc.	• • • •
4. Typed Name Kimberly Lowe		5. Date May 5, 1999	9/21/98			••••

EPA Form 8750-1 (Rev. 8-94) Previous editions are obsolete

White - EPA File Copy (original)

Yellow - Applicant Copy

NOTE TO THE JACKET

70871-R and 70871-E

9/21/98

Bioshield called about a week ago to say that 411578-03 (Acute Inhalation) had already been reviewed by the Agency and accepted. So I got the RED file from Julie and found two references which stated that it was accepted. We still wondered why it had been accepted when Wallace noticed what seemed to be critical deficiencies in this study. Julie gave me a Guideline Status Report from CRMS which also said the study had been accepted. After speaking with Wallace he suggested that I go over to CM2 (8th floor, HED, Caswell Room) and look up document 007667 which should be the review.

This review of MRID 411578-03 was done by Henry Spencer who noted the same deficiencies as Wallace but he felt that the study could be acceptable and a TOX category assigned once the purity of the test compound was provided. The RED states that this information was provided via FAX to be 72.1% and the study was upgraded to core minimum, which makes it an acceptable study.

I then went back to Wallace for a determination about whether they could bridge form this study. He wrote me the note that follows and gave it a category III for acute inhalation.

Dennis and I decided that Bioshield should cite 41157803, 93218014 (the summary MRID) and 93218038 (the reformat MRID) on their data matrix.

Tracy Lantz

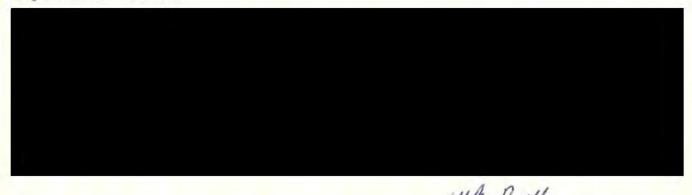
Team 31

Note to Tracy Lantz

09/18/98

In my opinion, products 70871-E and 70871-R BioShield AM 500 I and BioShield AM 500 -- which are equivalent formulations -- can be assigned (for labeling purposes) acute inhalation toxicity Category III based on the MRID 411578-03 study, which was reviewed by HED in 1990 and which I commented on in my 01/13/98 review re: 70871-G, -U, and -L. I rejected the study for failure to establish a toxicity Category. However, the study results indicate that the test material, at a 72% strength, is highly likely to be less severe than acute Category II. Since 70871-E and -R represent about a 14-fold dilution* of the product tested, I think that Category III can be assigned.

*In regard to the additional ingredient, I wrote the following in a previous review:



When Roll

Product ingredient source information may be entitled to confidential treatment

Manufacturing process information may be entitled to confidential treatment



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

00766

JAN - 5 1990

HED Document# 007667

OFFICE OF
PESTICIDES AND TOXIC SUBST

MEMORANDUM

SUBJECT: Review of 3 Studies Submitted: (a) Eye, (b) Skin

Irritation and (c) Inhalation on Dow Corning X-9-5700 to

Fulfill Reregistration Requirements

ID# 34292-1

Tox Chem. No.: 892B

Project No.: 9-2248

Record No.: 253085

.∋: Jim Wilson, P.M. #31

Registration Branch

Review Reregistration Division (H7508C)

FROM: Henry Spencer, Ph.D. 12/4/97

Review Section II

Toxicology Branch I - Insecticide, Rodenticide Support

Health Effects Division (H7509C)

THRU: Marion Copley, D.V.M., Section Head The Company of the P

Review Section II

Toxicology Branch I - Insecticide, Rodenticide Support

Health Effects Division (H7509C)

Conclusions:

- 1. The data submitted for eye and dermal irritation evaluations are a conglomerate of old summary data and are incomplete (MRID# 411578-01, MRID# 411578-02) and therefore are useless. These are data gaps.
- Only a more recent study (acute inhalation toxicity MRID# 411578-03) by Dow Corning was reviewed and classified as core supplementary.

Skin and Eye Irritation Studies (MRID# 411578-01 and 411578-02)

- 1. Individual data are missing, and importantly the skimpy information is incorrectly referred to as "Q9-5700 in MRID# 4115788-99. In either case these two pieces of "data" will not be reviewed as studies in their present condition: i.e., no inclusion of the number of animals used, and individual data and scores and source, age, etc. for the findings. These several toxicity areas remain data gaps.
- 2. Review of Acute Inhalation study with Dow Corning 5772 Compound in rats indicates that Dow Corning 5772 compound is of rather low inhalation toxicity. This remains a data gap and needs to be upgraded.

mary Review By:

Henry Spencer Jest 2/4/39 Section II, Toxicology Branch I/HED

Secondary Review by:

Marion Copley, DVM, Section Head Moply Section II, Toxicology Branch I/HED

DATA EVALUATION REPORT

Study Type:

Acute Inhalation Toxicity

Tox Chem. No. 892B

MRID No.: 411578-03 Project No.: 9-2248

Test Material:

Dow Corning 5772

Lots 2,3,4 from New Ventures TS&D purity not

stated

Mixed 20% by weight in distilled water

pH adjusted to 55 with glacial acetic acid

Study No.:

1312

Sponsor:

Dow Corning Corporation

Testing Facility:

Dow Corning Corp., Department of Toxicology,

Midland, MI 48640

Title of Report:

An Acute Aerosol Inhalation Toxicity Study with

Dow Corning 5772 Compound in Rats

Author:

C. B. Kolesar, W. H. Siddique and E. Stanton

eport Issued:

February 15, 1985

Conclusions:

In a 4 hr. exposure to 0.35 and 0.45 mg/L of Dow Corning 5772 test material as an aerosol toxicity noted was minimal and the LC50 was greater than 0.45 mg/L (HDT). Tox. Cat. II.

Core:

Supplementary - requested rational for such low test doses used. Purity of test compound not

provided. The study may be upgraded.

Methods

Male and female rats of the Sprague-Dawley strain weighing 175-200 gm. were purchased from Charles River and acclimated for 7 days prior to experimentation.

Animals were offered Purina Rodent chow and water libiturn excepting at exposure.

119

Temperature in observation rooms was 22+2 C and relative funidity was kept at 30-50%.

The animals were exposed in 450 liter chambers under dynamic conditions with 9-17 air changes per hour.

Spraying Systems Inc., Chicago, IL provided the aerosoling equipment.

Mass concentrations of the aerosol in the chamber was sampled each 30 minutes.

Particle size and ranges were determined using a cascade impactor.

Two control groups were used int he study. One control group of 5 per/sex was matched and studied concurrently with the 0.35 mg/L test group and the second was used concurrently the following day with the 0.45 mg/L test group.

After the 4 hr exposure, the animals were held for 14 days with observations only on the week days.

Body were determined prior to exposure and on days 1,2,4,7 and 14 post exposure.

Lungs were weighted when test animals were sacrificed. A signed QA statement was present.

Result

Relative humidity was elevated in the Test Dose II group over controls. Controls were in approximately 50% RH and the test group II (0.45 mg/L) was in an (TWA) average of 75% RH for the 4 hr. eriod.

Particle Size:

The particle size (geometric mean particle size (Micrometer) was 1.3+0.1 for the 0.35 mg/L test group and 2.3+0.1 for the 0.45 mg/L group.

Toxicity:

There were no deaths. Body weights were reduced significantly in males on days 1 and 2 post exposure in the Test 1 group and in both males and females at 1, 2 and 4 post exposure days in Test 2 animals.

Lung Weights:

Absolute and relative lung weights were increased (though not significantly) in the test group males and females.

Females in group 2 test animals produced slight (not statistically significant) decreases in absolute and relative lung weights. Lung weights in males were not consistent.

Conclusion:

The dose of 0.35 mg/L produced minimal toxicity as reduction in net gain for a short post exposure period.

Toxicity was more evident (weight loss) at 0.45 mg/L exposure. No deaths occurred at either dose throughout the exposure and observation period.

The LC_{50} is greater than 0.45 mg/L following a 4 hour exposure.

The study does not allow for a toxicity of less than Tox. Cat.II.

Purity of the D.C. 5772 compound must be provided.

Office of Pesticide Programs Chemical Review Management System Guideline Status Report

Page Number: 6

: 3148 Trimethoxysilyl quats

Case

Chemical : 107401 Trimethoxysilyl)pxopyl dimethy

Section: CRM: AD

Branch: AD

Number Name Company Number Name Guideline Due Date Guideline Status Study Study Study Submission Type 164911 42456511 130319 MRID 04/05/74 08/25/80 Received Date Review Date Acceptability Extraneous submission Extraneous submission Extraneous submission

Phase 3 Comment: A study (summary) with the 72% formulation (tested to limit dose) was submitted by FAX. This study is acceptable for review. Note: Once the Registrant officially submits this study a MRID No. will be assigned.

Acute dermal tox. rabb / / Acceptable/Satisfied

81-2

									-	×								
						81-4				81-3								
						Primary eye irration-r				Acute inhal, tox rat								
						11				11								
						Acceptable/Satisfied				Acceptable/Satisfied		המוש בשלמם והפערו	amstrondae brook on					
Study	Study	Study	Study	Study	Study		Study	Study	Study		Study	Me Study	Study	Study	Study	Study	Study	
								Study Reformat										
164911	130319	130320	130318	40385201	41157801		40385219	93218038	41157803		42456512	164912	130319	130318	40385201	41339402	43219901	
04/05/74	08/25/80	08/25/80	08/25/80	10/23/87	07/06/89		10/23/87	07/24/90	08/12/93			04/05/74	08/25/80	08/25/80	10/23/87	12/20/89	04/28/94	
				07/19/93	07/19/93		07/30/93	07/24/90 07/30/93	08/12/93						10/13/94		10/13/94	
Extraneous submission	Extraneous submission	Extraneous submission	Extraneous submission	10/23/87 07/19/93 Acceptable	07/06/89 07/19/93 Unacceptable		10/23/87 07/30/93 Unacceptable	Acceptable	08/12/93 08/12/93 Acceptable		Extraneous submission	Extraneous submission	Extraneous submission	Extraneous submission	10/23/87 10/13/94 Acceptable	Extraneous submission	04/28/94 10/13/94 Acceptable	

from the RED file for case # 3148

Case # 3148

PHASE FOUR REVIEW

(NOTE: This only contains additions and changes from the phase 2 response.)

Pesticide:

3-(Trimethoxysilyl)-

propyldimethyl-octadecyl

ammonium chloride

Transmitted to HED on: 12/03/92

Chemical#/Case#: 107401/819411

Tox. Chem #: 892B

Sponsor: DOW CORNING CORP. 107401

Submission No.: S430115

CRM: Bruce Sidwell

Phone #: 308-8078

Branch: Toxicology Branch I

Reviewer: John C. Redden

Completed: 02/23/93

Concurrence:

Division Director's Concurrence 2 2/26/4, Denna-Cum 2/26/4

Are there any changes from the reviews in phase 2?

NO YES

(see below)

Summary:

Tier 1 Data Gaps:

The following missing studies or data are needed to complete this package:

1) Guideline 83-3 Teratogenicity (1st species: rat or rabbit) An upgradable study with Dow Corning 5700 Hydrolysate exists (missing purity).

Note: we are currently not requiring Tier 2 and 3 studies. However, they may be triggered depending on Tier 1 results, and the Agency reserves the right to require the below listed studies.

Tier 2 Studies (not Data Gaps but may be required):

- 1) Guideline 82-1 90-day feeding/rodent
- 2) Guideline 83-3 Teratogenicity (2nd species)
- 3) Guideline 85-2 Dermal Penetration; upgradable study present

Tier 3 Studies (not Data Gaps but may be required):

1) Guideline 83-1 Chronic feeding (2 species); only if it is determined that the margin of safety is less than 1000 based on the subchronic data, and exposure cannot be reduced.

- 2) Guideline 83-2 Oncogenicity (2 species); required if the Agency determines from the mutagenicity test battery that the AI may pose an oncogenic risk, or based on dermal exposure times the Q* of unity the calculated risk is unacceptable.
- 3) Guideline 83-4 Metabolism; only if the metabolism of the chemical is necessary to clarify unusual effects observed in chronic or reproduction studies to clarify issues concerning structure activity relationships.

Response, by Guideline

Guideline #: 81-1

Acute oral/rat

1. MRID #:93218011, 93218010 (Dup of -11), 40385201 Study #:AD-0003

Discussion/Recommendation:

Summary of MRID 40385201 submitted to the Agency, the study was previously reviewed, and core graded Minimum (HED Document#006796, 002486). The following deviations were noted: 1) individual observations done on day 1, 7 and 14; and 2) gross necropsy not done. However, due to the high LD_{50} (12.27 g/kg) it is not necessary to repeat the study and it remains core graded Minimum. Requirement satisfied.

2. MRID #:93218049, 42456511 Study #:

Discussion/Recommendation:

DOW CORNING 5772; this study is tentatively accepted for review.

Guideline #: 81-2

Acute dermal/rabbit

1. MRID #:93218024, 42456512, 41339402

Study #:

Discussion/Recommendation:

New submission; the Registrant submitted a 14-day range finding dermal study in rats for Guideline 81-2. The following deviations from 81-2 exist: 1) 2 animals/sex/group (5 animals/sex/group); 2) animals dosed for five consecutive days a week for fourteen days (Dosing, single dermal); and 3) material left in contact for a period of 6 hours/day, 5 days per week. The highest dose group tested was 1,000 mg/kg/day. The material was suspended in propylene glycol. Quoting the study: "No overt signs of toxicology or mortality were seen in any of the groups. No significant differences in mean body weights or food consumption were observed between treated and control animals. Also, no treatment-related effects were noted at gross necropsy."

2. MRID #:
Study #:
Discussion/Recommendation:

The registrant submitted by vax an acceptable for review study (summary) with the 72% formulation (tested to limit dose). This study is acceptable for review. Note: Once Registrant submits study a MRID NO will be assigned.

Guideline #: 81-3

Acute inhalation/rat

1. MRID #:93218008, 9318025, 40385219

Study #:

Discussion/Recommendation

Reformat of MRID No. 40385219 previously submitted to the Agency. However, this study does not appear in the Tox One-Liners. Study to determine respirable particle size. This study is unacceptable for review.

2. MRID #: 93218014, 41157803 Study #: Dow Corning Corp 1312 Discussion/Recommendation:

Summary of MRID 41157803 previously submitted and reviewed by the The study was core graded Supplementary Document #007667), and was upgradable if purity was supplied. This summary states purity to be 72.1% The Registrant supplied additional information by vax that allows this study to be upgraded to Minimum.

Guideline #: 81-4

Primary eye irritation/rabbit

1. MRID #:93218017, 40385201 study #: AD-0003 Discussion/Recommendation

Summary of MRID 40385201 previously submitted and reviewed by the Agency, and core graded Minimum (HED Document#006796, 002486). The following minor deviation was noted: left eye washed within 30 seconds of dosing and right eye washed 1 hour post dosing (24 hours required in quideline). Requirement satisfied.

2. MRID #:93218015; 41157801 Study #:

Discussion/Recommendation

Summary of MRID 41157801 previously submitted to the Agency. However, this study does not appear in the TOX ONELINERS. The following deviations were noted: 1) only 1 rabbit used (guideline requires 6); and 2) left eye washed within 30 seconds of dosing and right eye washed 1 hour post dosing (24 hours required in guideline). The study is Core Supplemental and not upgradable.

study #: 3. MRID #:93218016, 41157802 Discussion/Recommendation

Summary of MRID 41157802 previously submitted to the Agency. However, this study does not appear in the TOX ONELINERS. The following deviations were noted: 1) only 1 rabbit used (guideline requires 6); and 2) left eye washed within 30 seconds of dosing and right eye washed 1 1/2 hours post dosing (24 hours required in guideline). The study is Core Supplemental and not upgradable.

Guideline #: 81-5

Primary dermal irritation/rabbit

from the RED file for case # 3148

Response to Phase 3 Submission 08/12/93

Pg. 7

Chemical/Case Number | Company Number / Name | 107401 / 3148 | 034292 | DOW CORNING CORP.

GDLN #

DESCRIPTION

REGISTRANT'S COMPLIANCE/MRID

EPA DECISION

MRID Comments Continued:

toxicity in rats.

The following deviations exist:

2 animals/sex/group (5 animals/sex/group);

2) animals dosed for five consecutive days a week for fourteen days (Dosing, single dermal); and
3) material left in contact for a period of 6 hours/day, 5 days per week. The highest dose group tested was 1,000 mg/kg/day. The material was

suspended in propylene glycol.

81-2 Acute dermal tox. rabbit/rat 42456512-St

Comments: This submission was reviewed with MRID 41339402.

Please see the comments for MRID 41339402.

81-3 Acute inhal. tox rat 40385219-St Denied/Def.

Comments: This study is unacceptable for review

1-3 Acute inhal. tox rat 93218038-Re Accept

81-3 Acute inhal, tox rat 41157803-St Accept

Comments: Summary of MRID 41157803 previously submitted and

reviewed by the Agency. The study was graded core Suplimentary, and was upgradable if the purity was supplied. This summary states the purity to be 72.1%. The Registrant supplied additional information by FAX

that allows this study to be upgraded to core

Minimum.

81-4 Primary eye irration-rabbit 40385201-St Accept

Comments: Summary of MRID 40385201 previously submitted and

554310. Submission No. Data Package No. D246364 FAPA CODING FORM FOR APPLICATIONS FOR RECISTRATION/AMENDMENTS File Symbol/Reg. No. 70871-EPH 31 Action Code 187 old chemical MINOR 10 Descriptor (Amend/Resultations only) charge |5 | Intrastate Call-in / / (Y) Yes |15 | Child-resistant / /(C) Certification Packaging / / (N) NO / /(S) Service Person (R) Non-residential |20| Registration Type: days (1) Conditional / (2) Unconditional / (N) Not-Applicable | 25 | Proposed Classification: | 30 | Final Classification: / / (R) Restricted / / (R) Restricted Due Date: 9/4/98 (N) Not Classified / / (G) General |35| Date on Application: |04| EPA Received Date: |40 | Date Received by PH |80| Method of Support: // (1) Cite-All // (6) Owner Submission / / (4) Not Applicable / / (7) Total Submission / / (5) Not Submitted / / (8) Selective Method DATE WE DATE RESPONSE Reviewers Requested: SENT DATE RETURNED CODE CH EF PL DEB NDEB TB EEB EFGB 1115 FINAL |120 | Response Response 75-DAY RESPONSE QUE DATE: //(Y) Yes //(N) No

Reviewer ID

127

SEP 0 4 1998

BioShield Technologies, Inc. 4405 International Boulevard, Suite B109 Norcross, GA 30093

ATTENTION: Kimberly Lowe

Agent for BioShield

SUBJECT:

BioShield AM 500 I

EPA File Symbol 70871-E

Your Application for Registration Dated: May 5, 1998

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to register 70871-E is unacceptable.

The submitted primary eye irritation study (MRID# 44553501) has been reviewed and is acceptable to support this registration.

Your product has not fulfilled the requirement for an Acute Inhalation study as per Guideline 81-3. We will not accept a waiver for this requirement, particularly in light of your directions for use which state that this product may be applied by spraying or fogging. Your correspondence stated that there was existing data in the form of MRID# 41157803. Refer to our correspondence on 70871-G, 70871-U, and 70871-L of 1/13/98 (see enclosure). Based on a cursory review of this study (MRID# 41157803), the number and spacing of the dose concentrations were not appropriate for the calculation of an LC50, there was not a third concentration, and there was no mortality, therefore this study is unacceptable. This requirement must be addressed by submitting a study or by citation of data. In either case submit a revised Certification with Respect to Citation of Data form along with a complete Data Matrix which includes all of the data you have cited for this product. Submit the new forms as per PR Notice 98-5.

Your product has not fulfilled the requirement for a Dermal Sensitization Study as per									
		1-6. Refer to	the same corre	essonduneen	senoted above.	We will not	waive the		
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EPA Form 1320-1A (1/90)

requirement for this study. Your correspondence stated that there was existing data in the form of MRID# 42197401. This study appears to be acceptable based on a cursory review and therefore we will tentatively classify this as a non-sensitizer. Thus, this data requirement can be fulfilled by referencing this study (MRID# 42197401) on your revised data matrix.

The current toxicity profile for this product is as follows:

Acute Oral Toxicity IV
Acute Dermal Toxicity III

Acute Inhalation Toxicity Not Satisfied

Primary Eye Irritation II
Primary Skin Irritation III

Dermal Sensitization Non-Sensitizer

Storage and stability studies are still required for this product. Please advise the Agency as to the status of this testing.

Your proposed label has been discussed with our efficacy branch. Due to the perception that the terms "antibacterial" and "antimicrobial" are implied to impart public health benefits, ALL references to either of those terms on this label must be changed to any of the following terms: mildewstat, microbiostat, bacteriostat, fungistat, or preservative. Note that your label includes the term "antimicrobial" in the following locations (in addition to the specific changes listed below): page one immediately following the product name, page one of the collateral labeling section at the top of the page, and page two of the collateral labeling in the last paragraph (two occurrences). Each time this term appears it must be changed or deleted from you label.

Based on their comments, the following additional changes must be made to your label.

- 1) On page three the statement "The active ingredient in AM 500 I is effective against fungi (including mold and mildew), algae, and yeasts." must be changed to read as follows "The active ingredient in AM 500 I is effective against fungi (including mold and mildew) and algae as a static agent." A claim against yeast is considered a public health claim, thus if you would like yeast included on the label, submit a protocol to the Agency for review prior to submitting a study.
- 2) On page three the statement "AM 500 I can be used for incorporation into and treatment of the following items or substrates to impart durable antimicrobial protection:" must be changed to read as follows "AM 500 I can be used for incorporation into and treatment of the following items or substrates to impart *bacteriostatic/fungistatic activity*."
- 3) On page one of your collateral labeling the statement "Primary Uses.....As an active ingredient for formulating microbiocides for use in laundry additives, carpet treatment products, upholstery and drapery treatment products, and building and cleaning treatment products to give a surface-durable antimicrobial treatment" must be revised to read as follows "Primary Uses.....As an active ingredient for formulating microbiocides for use in laundry additives, carpet

SYMBOL SURNAME DATE

DATE

Treatment products, upholstery and drapery treatment products to give a bacteriostatic,

SYMBOL DATE

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fungistatic, mildewstatic activity."

- 4) On page two of the collateral labeling the statement "Good durability-BIOSHIELD AM 500 I Antimicrobial Agent imparts durable biostatic activity to the surface of a wide variety of substrates; it is leach-resistant and nonmigrating and is not consumed by microorganisms." must be revised as follows "Good durability-BIOSHIELD AM 500 I imparts biostatic activity to the surface of a wide variety of substrates."
- 5) On page two of the collateral labeling the statement "Provides hygienic freshness and combats deterioration caused by bacteria, fungi, algae, and yeasts." must be revised as follows "Provides freshness and combats deterioration caused by bacteria, fungi, and algae."
- 6) On page three of the collateral labeling the statement "The active ingredient in AM 500 I is effective against fungi (including mold and mildew), algae, and yeasts." must be changed to read as follows "The active ingredient in AM 500 I is effective against fungi (including mold and mildew) and algae as a static agent."
- 7) On page three of the collateral labeling the statement "AM 500 I can be used for incorporation into and treatment of the following items or substrates to impart durable antimicrobial protection:" must be changed to read as follows "AM 500 I can be used for incorporation into and treatment of the following items or substrates to impart bacteriostatic/fungistatic activity."

The following additional labeling comments also apply:

- A) Due to the fact that this is a manufacturing use product, detailed directions for use must <u>not</u> be included on your label. Therefore, in the "Directions For Use" section of the main label and the collateral labeling, delete the entire statement beginning with "AM 500 I can also be diluted by adding 0.2 to 2 fluid ounces..." and ending with "...to give a final treatment of 0.1 to 1.0 percent by weight active ingredient." Also delete the paragraph beginning with "After applying the antimicrobial agent..." and ending with "...should be determined for each application before use."
- B) Our 2/5/98 correspondence on this product asked you to remove the following sites "building materials, concrete and materials used to make concrete, and fibers, such as polypropylene fibers, and fabrics made from those fibers used for incorporation into concrete" on page three of the label revise the statement "AM 500 I is approved for use in formulating microbiocides for use in laundry additives, carpet treatment products, upholstery and drapery treatment products, and building cleaning and treatment products." should be revised as follows "AM 500 I is approved for use in formulating *microbiostats* for use in laundry additives, carpet treatment products, upholstery and drapery treatment products." Your label no longer has sites appropriate for "building cleaning and treatment products." The statement at the top of page three of the collateral labeling must be revised in the same manner.
- C) Clarify as to what size containers will be used when marketing this product. Your Application for Pesticide form 8570-1 does not agree with your proposed label.

EPA Form	1320-1A (1/90)			Printed on Recycles	Paper		OFFICI	ASQUE CODA			
DATE											
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	as follows. Delete the sentence "Do not ap a sentence water or to areas where surface water										
D) Revise the "Environmental Hazards" section of the main label and collateral labeling											

is present or to intertidal areas below the mean high water mark." Replace this sentence with "This pesticide is toxic to fish."

E) Make the following changes to your "Storage and Disposal" statements of both the main label and the collateral labeling. Propose a revised Pesticide Disposal section by referring to the label Review Manual and PR Notice 83-3. Revise the Container Disposal by specifying that your current statement is for <u>Plastic Containers</u>. Then include the following statement noting that it is appropriate for <u>Metal Containers</u> "Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities."

Due to the above mentioned requirements for further Toxicity Data, neither the "Statement of Practical Treatment" nor the "Precautionary Statements" can be addressed at this time.

The agency reserves a full label review until the above issues have been addressed.

Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,

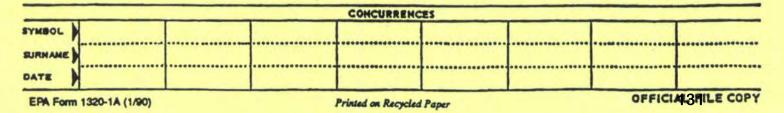
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Tracy Landy
Velma Noble

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510W)

7510W:T.Lantz:9/1/98:70871-E





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

JAN 1 3 1998

MEMORANDUM

Subject:

BST Protectant Concentrate C15

EPA File Symbol 70871-G Data Package D239768

BST Protectant 50

EPA File Symbol 70871-U Data Package D239765

BST Protectant 75

EPA File Symbol 70871-L Data Package 0239760

From:

Wallace Powell, Biologist

Risk Assessment and Science Support Branch

Antimicrobials Division (7510W)

Thru:

Laura E. Morris, Team Leader Laura E. Morris

Risk Assessment and Science Support Branch

Antimicrobials Division (7510W)

Norman Cook, Chief

Risk Assessment and Science Support Branch

Antimicrobials Division (7510W)

To:

Velma Noble, Product Manager, Team 31 Zenobia Jones, Team Reviewer, Team 31

Registration Branch I Antimicrobials Division

BACKGROUND

The applicant, BioShield Technologies, Inc. (as represented by Jellinek, Schwartz & Connolly, Inc.), has applied for registration of BST Protectant Concentrate C15, BST Protectant 50, and BST Protectant 75, three manufacturing-use products proposed for incorporation into anti-microbial products that are

used in cleaning products, textile and building treatment products, and a variety of manufactured items. The applicant has submitted a request for waivers of all product acute toxicity testing, and has cited several studies to show that existing data are sufficient to support registration.

DISCUSSION

According to a December 4, 1997 EPA memorandum from Timothy McMahon to Velma Noble, the following data is available for the active ingredient contained in these products. The memorandum notes that these tests were conducted on a 50% formulation.

Study Type	MRID No.	Tox. Category
Acute Oral Toxicity	403852-01	IV
Acute Dermal Toxicity	403852-01	III
Primary Eye Irritation	403852-01	I
Primary Dermal Irritation	403852-01	III

The subject products are water dilutions of a product resembling the product for which the studies cited in this memorandum were submitted. The dilution factors are rather large.

In support of registration of the subject products, the applicant has cited the above MRID 403852-01 and several additional studies also: 424565-11 (acute oral toxicity), 432199-01 (acute dermal toxicity), 411578-03 (acute inhalation toxicity), 932180-47 and 424565-13 (primary dermal irritation), and 421974-01 (dermal sensitization). Of these, according to our records, the acute oral toxicity study, MRID 424565-11, has been reviewed previously with a Toxicity Category IV result (LD₅₀ = 12.27 g/kg), which is in agreement with the result in the list above. Because this is the Category of lowest toxicity, Category IV can be assigned to the subject products.

The acute dermal toxicity study with MRID No. 432199-01 is also not being reviewed for this memorandum. The study listed above with MRID No. 403852-01 was assigned Category III for acute dermal toxicity, and this Category can be assigned to the subject products for labeling purposes.

Based on a cursory review of the acute inhalation study, MRID No. 411578-03, the number and spacing of the dose concentrations were not appropriate for the calculation of an LC_{50} . Two dose concentrations were used (both within the Toxicity Category II

range). There was no third concentration, and there was no mortality which could be used for calculating an LC_{50} . The study is therefore not acceptable. An acceptable acute inhalation study is required, as conducted on the subject product formulations, as represented by BST Protectant Concentrate C15 (since its concentration is the highest of the three products).

As for primary eye irritation, Toxicity Category I is listed above for the concentrated material, but it is not known what Toxicity Category would result from the dilution represented by the subject products. Therefore an acceptable eye irritation study is required, as conducted on the subject product formulation. To reflect the source material's Category I rating for eye irritation in the BioShield products may result in a significant overstatement of the hazard.

As for the primary dermal irritation studies with MRID Nos. 932180-47 and 424565-13, based on a cursory review of the studies it was noticed that individual animal data was not included, and observations ended at 72 hours in spite of the presence of significant irritation. The two studies suggest a Toxicity Category of I or II for primary dermal irritation. This is not in agreement with the Category III indicated for the MRID 403852-01 study listed above. Thus, the dermal irritation assessment is inconclusive, and a study is required for the diluted material.

The cited dermal sensitization study, MRID No. 421974-01, appears acceptable based on cursory review, indicating no sensitization response for the concentrated material. Therefore, the study is applicable to the subject product as well, acceptable on a tentative basis, until a complete review is conducted in the reregistration process. (It is this reviewer's intention to provide a review report well prior to that time.)

CONCLUSION

As per the foregoing discussion, the following Toxicity Categories can be assigned to the subject product for purposes of determining appropriate precautionary labeling.

Note that if the outcomes of the evaluations as a part of the Reregistration process (which are not yet completed) differ from these Toxicity Categories listed below, new data will be required.

Acute Effect

Acute Oral Toxicity

Acute Dermal Toxicity

Acute Inhalation Toxicity

Primary Eye Irritation

Primary Dermal Irritation

Dermal Sensitization

Category

ΙV

III (assigned)

Study is required

Study is required

Study is required

Non-sensitizer (tentative)

The precautionary labeling requirements for the subject product will be determined once the acute toxicity data requirements have been fulfilled.



To:

OPP AD

CC:

Subject: Efficacy Claims

This is a subject which should be expanded and discussed in more detail at a future training session. However, the following is being offered to provide guidance in the area of efficacy labeling claims.

- 1. The terms, "disinfectant," "germicide," "bactericide," "fungicide," "virucide," and "sanitizer," as supported by appropriate efficacy data, are limited to public health products.
- 2. The terms, "bacteristat," "fungistat," "microbiostat," and "preservative" (not preventative) are limited to non-public health products.
- 3. You will note that the suffix "cide" corresponds with the killing abilities of public health products while the suffix "stat" corresponds with the inhibiting abilities of non-public health products. Two notable exceptions are the term "microbiocide" which has long been associated with water treatment slimicides and the term "mildewcide" which has long been associated with paint and coatings additives.
- 4. The terms "antimicrobial" and "antimicrobial agent" should be limited to end-use public health products and to manufacturing-use products which can be reformulated into both public and non-public health uses. Examples of the latter are the labels for technical o-phenylphenol and glutaraldehyde.
- 5. The term "antibacterial" should be limited to end-use public health products.
- 6. This criteria should also be followed when approving additional brand names. You are reminded that terms such as "germ proof" and "algae free" are prohibited by the Subdivision H Labeling Guidelines and that brand names with claims of heightened efficacy, whether or not they are qualified by the term "brand," are limited in their use by PR Notice 93-6.
- 7. In conclusion, please be aware that it is very difficult, maybe impossible, to reverse a labeling approval once it has been made.

On a totally unrelated matter, you will read in the upcoming Weekly Report an article about the Isolyser Corporation. For the benefit of those of you who are not familiar with the issues associated with medical waste disposal, this is a major accomplishment for the antimicrobial program and for the American public in general. While many people inside and outside of the division have worked for many years on this matter, full credit should be given to Yvette Hopkins for communicating with and resolving matters associated with state medical waste regulatory programs and her perseverance in working with Region 2 and OECA to resolve the Red-Z solidifier enforcement case. A final resolution of the Isolyser case would not have been possible without her efforts.

oloco mildeustatic microbiostatic backviostatic fungistatic preser vetive

No antibucterial BioShield AM 500

walter No

ANTIMICROBIAL AGENT & PROTECTANT
A Silicone Quaternary Ammonium Salt
(For Manufacturing Use Only)

5.0	95.0%		100.0%
3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride			100.09
Active Ingredient:	Inert Ingredients:	TOTAL	INGREDIENTS:

KEEP OUT OF REACH OF CHILDREN WARNING

Lot No. EPA Reg. No. xxxx-xx

EPA EST. xxxxx-GA-xx

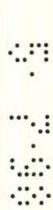
NET CONTENTS: 2, 4, 8, 16, 20, 22, or 36 fluid oz.; 1, 5, 55, 150, or 300 gal. - daring. docent agree up appl. Ac perficiel

STATEMENT OF PRACTICAL TREATMENT

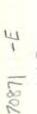
IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention. attention.

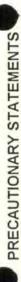
person. Drink promptly a large quantity of milk, eggwhites, gelatin solution, or, if these are not available, drink large quantities of IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious water. Avoid alcohol.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.



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HAZARDS TO HUMANS AND DOMESTIC ANIMALS

through skin or inhaled. Do not get in eyes, on skin, or on clothing. Avoid breathing vapor. Wear protective clothing and gloves, and protective eyewear (goggles or face shield). Wash thoroughly with soap and water after handling and before eating, drinking, Warning. Causes substantial but temporary eye injury. May be fatal if swallowed. Causes skin irritation. Harmful if absorbed using tobacco, or using the toilet. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

This prestrictures toxic to fish,

previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in colloteral labeling stoudd agree

De-activation of AM 500 I can be achieved by the addition of anionic surfactant in quantity equivalent to that of AM 500 I.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

AM 500 I can be incorporated directly into formulations used to make the end products listed under "approved uses." No Dennis

AM 500 I can also be diluted by adding 0.2 to 2 fluid ounces AM 500 I per cup (3.2 to 32 fluid ounces AM 500 I per gallon) of water padding, soaking, spraying, fogging or by using loam finishing techniques to give a final treatment of 0.1 to 1.0 percent by weight or other solvents (for example, alcohol and ketones) and then applied to organic or inorganic substrates by brushing, dipping, active ingredient.

No Dennis

After applying the antimicrobial agent, the substrate can then be dried at temperatures from ambient to a maximum of 160° C (320° Optimum application and drying conditions, such as time and temperature, should be determined for each application before use. F) to effect complete condensation of silanol graups and to remove water, solvents and/or traces of methanol from hydrolysis.

For formulating use into end-use products.

AM 500 I is approved for use in formulating microbiocides for use in laundry additives, carpet treatment products, upholstery and drapery treatment products, and building cleaning and treatment products.

→as a static agent. The active ingredient in AM 500 I is effective against fungi (including mold and mildew), algae, and yexsts.

AM 500 I can be used for incorporation into and treatment of the following items or substrates to impart durable antimicrobial protection

bacteriostatic Air filters for furnaces, air-conditioners, air purification devices, automobiles, recirculating air handling systems;

fugistatic

- Air filters/materials;
- Aquarium filter material;
- Bed sheets, blankets, and bedspreads;
 - Buffer pads (abrasive and polishing);
 - Carpets and draperies;
- Fiberfill for upholstery, sleeping bags, apparel, etc., where the fiber is cotton, natural down, nylon, polyester, rayon, or wool;
 - Fiberglass ductboard;

30

- Fire hose fabric;
- Humidifier belts;
- Mattress pads and ticking;
- Men's underwear and outerwear;
- Non-woven disposable diapers;
- Non-woven polyester;
- Outerwear apparel;
- Disposable polyurethane foam cushions for Lapidus Airfloat Systems;
- Polyurethane foam for household, industrial, and institutional sponges and mops;
 - Polyurethane and polyethylene foam, when covered;
- Polyurethane foam for packaging and cushioning in non-food contact applications;
 - Polyurethane foam used as a growth medium for non-food crops and plants;
- Pre-moistened towelettes and tissue wipes (these do not impart pesticidal properties);
- Roofing materials defined as shingles, roofing granules, wood shakes, felt, stone and synthetic overcoats;
 - Sand bags, tents, tarpaulins, sails, and ropes;
- Athletic and casual shoes;
- Shoe insoles;
- Shower curtains;
- Socks comprised of nylon, nylon/orlon, cotton/nylon, linen/Lycra, acrylic/polypropylene/nylon/Lycra, wool/silk/nylon/Lycra and wool/acrylic/nylon/Lycra;
- Throw rugs;
- oweling made of 100 percent cotton, 100 percent polyester, and blends of the two fibers;
 - Toilet tank and seat covers;
 - · Umbrellas;
- Upholstery made of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polyolefins, polypropylene, rayon, spandex, vinyl, and wool;
- Vacuum cleaner bags and filters;

- Vinyl paper-wallpaper for non-food contact saces;
- Disposable wiping cloths that can be used for multiple purposes such as dusting or washing furniture, cars, walls, windows, floors, appliances, dishes, counter tops, etc.; the wiping cloths do not impart pesticide properties;
 - Women's hosiery; and
- Women's intimate apparel.

EPA REGISTRATION REQUIREMENTS

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The applications for which this product is used may require approval by the Environmental Protection Agency on an end-use basis in regard to claims made thereof. Formulators are responsible for satisfying registration requirements for their products.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

inaccessible to children and away from food or feed. AM 500 I has a minimum shelf life of 12 months from the date of shipment Pesticide Storage: Store in original, tightly closed containers below 30°C (86°F) and above 0°C (32°F) in a secure area

toxic as per 64881-5 label

violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide Pesticide Disposal: Pesticide wastes are acutely that are acutely that are acutely and a second of excess pesticide, spray mixture, or rinsate is a or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance. Mobal + Plastic L Sepande Statemonss for each

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

FOR MORE INFORMATION CONCERNING THIS PRODUCT, PLEASE CONSULT THE MATERIAL SAFETY DATA SHEET (MSDS). THE MSDS CAN BE OBTAINED BY WRITING BIOSHIELD TECHNOLOGIES, INC. AT 4405 INTERNATIONAL BOULEVARD, SUITE B109, NORCROSS, GEORGIA, 30093.

IMPORTANT: WARRANTY AND DISCLAIMER INFORMATION

BioShield Technologies, Inc., warrants that the product conforms to its chemical description and is reasonably fit for the purposes stated in this bulletin when used in accordance with directions under normal conditions of use; but this warranty of fitness for a particular purpose does not extend to the use of this product contrary to bulletin instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to seller, and buyer assumes the risk of any such use. BIOSHIELD SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING THE WARRANTY OF MERCHANTABILITY.

COLLATERAL LABELING

BioShield Technologies, Inc.

4405 International Boulevard, Suite B109 Norcross, GA 30093

bacteriastatic, fungistatic, mildenstatic activity

Information About Antimicrobial Agents

TYPICAL PROPERTIES

These values are not intended for use in preparing specifications

Structure...

Structure...

[(CH₃O)₃Si(CH₂)₃N-C₁₈H₃₇]⁺Cl⁻

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DESCRIPTION

AM 500 I is BioShield's designation for 3-(trimethoxysilyI) propyloctadecyldimethyl ammonium chloride containing 5 percent active ingredient by weight. Alkoxysilanes of this nature have been shown to form durable bonded coatings to a number of materials (see "References" section).

AM 500 I offers users the following features:

- Good durability—BIOSHIELD AM 500 I Antimicrobial Agent imparts durable biostatic activity to the surface of a wide variety of substrates; it is leach-resistant and nonmigrating and is not consumed by microorganisms.
- Increased efficiency—through proper application, durable bacteriostatic, fungistatic and algistatic surfaces can be attained with a minimum amount of AM 500 I.

3

BENEFITS

The following benefits are derived when a formulation containing the active ingredient is applied to a surface:

- Provides hygienic freshness and combats deterioration caused by bacteria, fungi, algae, and yeasts.
- Inhibits growth of bacteria and mildew on the treated article.
- Prolongs the life of a article by inhibiting the growth of bacteria and mildew.
- Resists development of bacterial and fungal odors.
- Retains freshness by resisting the growth of odor-causing bacteria and mildew (fungus).
- Provides a chemical treatment that enables fabrics to resist odors.
- Provides a unique chemical treatment that resists mildew and bacteria growth and imparts odor resistance.
- Product performance with little degradation up to 375°F.

Materials treated with formulations containing the antimicrobial agent AM 500 I are preserved by the bacteriostatic, fungistatic and algistatic action imparted by the active ingredient. AM 500 I inhibits the growth of microorganisms that are responsible for causing odor, discoloration and deterioration. It also provides residual inhibition of microorganisms to aid in the control of these deleterious effects. AM 500 I forms a coating on a wide variety of substrates and antimicrobial action is exhibited on contact.

water would allow

APPROVED USES

AM 500 I is approved for use in formulating microbiocides for use in laundry additives, carpet treatment products, upholstery and drapery treatment products, and building cleaning and treatment products.

The active ingredient in AM 500 I is effective against fungi (including mold and mildew), algae, and yeasts.

AM 500 I can be used for incorporation into and treatment of the following items or substrates to impart durable antimicrobial protection:

- Air filters for furnaces, air-conditioners, air purification devices, automobiles, recirculating air handling systems;
- Air filters/materials;
- · Aquarium filter material;
- Bed sheets, blankets, and bedspreads;
- Buffer pads (abrasive and polishing);
- Carpets and draperies;
- Fiberfill for upholstery, sleeping bags, apparel, etc., where the fiber is cotton, natural down, nylon, polyester, rayon, or wool;
- Fiberglass ductboard;
- Fire hose fabric;
- Humidifier belts:
- · Mattress pads and ticking;
- Men's underwear and outerwear;
- Non-woven disposable diapers;
- Non-woven polyester;
- Outerwear apparel;
- Disposable polyurethane foam cushions for Lapidus Airfloat Systems;
- Polyurethane foam for household, industrial, and institutional sponges and mops;
- Polyurethane and polyethylene foam, when covered;
- Polyurethane foam for packaging and cushioning in non-food contact applications;
- Polyurethane foam used as a growth medium for non-food crops and plants;
- Pre-moistened towelettes and tissue wipes (these do not impart pesticidal properties);
- Roofing materials defined as shingles, roofing granules, wood shakes, felt, stone and synthetic overcoats;
- Sand bags, tents, tarpaulins, sails, and ropes;
- Athletic and casual shoes;
- · Shoe insoles;
- Shower curtains;
- Socks comprised of nylon, nylon/orlon, cotton/nylon, linen/Lycra, acrylic/polypropylene/nylon/Lycra, wool/silk/nylon/Lycra and wool/acrylic/nylon/Lycra;
- Throw rugs;
- Toweling made of 100 percent cotton, 100 percent polyester, and blends of the two fibers;
- Toilet tank and seat covers;
- Umbrellas;
- Upholstery made of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polyolefins, polypropylene, rayon, spandex, vinyl, and wool;
- Vacuum cleaner bags and filters;
- Vinyl paper-wallpaper for non-food contact surfaces;
- Disposable wiping cloths that can be used for multiple purposes such as dusting or washing furniture, cars, walls, windows, floors, appliances, dishes, counter tops, etc.; the wiping cloths do not impart pesticide properties;
- Women's hosiery; and
- Women's intimate apparel.

ok wlo directions for

DIRECTIONS FOR USE

AM 500 I can be incorporated directly into formulations used to make the end products listed in this bulletin.

AM 500 I can be diluted by adding 0.2 to 2 fluid ounces of AM 500 I per cup (3.2 to 32 fluid ounces of AM 500 I per gallon) of water or other solvents (for example, alcohol, and ketones) and then applied to organic or inorganic substrates by brushing, dipping, padding, soaking, spraying, fogging or by using foam finishing techniques to give a final treatment of 0.1 to 1.0 percent by weight active ingredient.

After applying the antimicrobial agent, the substrate can then be dried at temperatures from ambient to a maximum of 160° C (320° F) to effect complete condensation of silanol groups and to remove water, solvents and/or traces of methanol from hydrolysis. Optimum application and drying conditions, such as time and temperature, should be determined for each application before use.

PRECAUTIONARY STATEMENTS

Warning. Causes substantial but temporary eye injury. May be fatal if swallowed. Causes skin irritation. Harmful if absorbed through skin or inhaled. Do not get in eyes, on skin, or on clothing. Avoid breathing vapor. Wear protective clothing and gloves, and protective eyewear (goggles or face shield). Wash thoroughly with soap and water after handling and before eating, drinking, using tobacco, or using the toilet. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

Inactivation of solutions containing AM 500 I may be accomplished by one of the following methods:

- addition of an anionic surfactant or detergent in quantity equivalent to that of AM 500 I in solution; or
- addition of Triton X-100 nonionic detergent at a final concentration of 10,000 ppm (1.0 percent volume/volume) or greater to bath solutions up to 1.0 percent volume/volume of AM 500 I.

Every effort should be made to contain accidental spills of AM 500 I to the immediate area. This may be accomplished by the use of sandbags to confine the spill to facilitate cleanup and disposal. Contaminated sand may then be disposed of by burial in an approved landfill. Many spills may be cleaned up with rags by wiping and/or mopping and allowing the liquid to absorb into the fabric. The rags may then be disposed of by incineration.

Floor drains in areas of material use should be protected with sandbags to contain accidental spills.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in original, unopened containers below 3°C (86°F) and above 0°C (32°F). AM 500 I has a minimum shelf life of 12 months from the date of shipment from BioShield.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Before handling, read product label in its entirety

IMPORTANT: WARRANTY AND DISCLAIMER INFORMATION

BioShield Technologies, Inc., warrants that the product conforms to its chemical description and is reasonably fit for the purposes stated in this bulletin when used in accordance with directions under normal conditions of use; but this warranty of fitness for a particular purpose does not extend to the use of this product contrary to bulletin instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to seller, and buyer assumes the risk of any such use.

BIOSHIELD SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING THE WARRANTY OF MERCHANTABILITY.

REFERENCES

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BioShield Technologies, Inc. 4405 International Boulevard, Suite B109 Norcross, GA 30093

4405 International Boulevard, Suite B109 Norcross, GA 30093

BioShield Technologies, Inc.

BioShield AM 500

ANTIMICROBIAL AGENT & PROTECTANT

A Silicone Quaternary Ammonium Salt (For Manufacturing Use Only)

92.0% 100.0% 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride...... Active Ingredient: Inert Ingredients: INGREDIENTS:

KEEP OUT OF REACH OF CHILDREN WARNING

EPA Reg. No. xxxx-xx

Lot No.

EPA EST. xxxxx-GA-xx

NET CONTENTS: 2, 4, 8, 16, 20, 22, or 36 fluid oz.; 1, 5, 55, 150, or 300 gal.

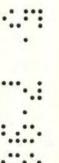
STATEMENT OF PRACTICAL TREATMENT

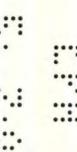
IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.

person. Drink promptly a large quantity of milk, eggwhites, gelatin solution, or, if these are not available, drink large quantities of IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious water. Avoid alcohol.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

Note to Physician: ... " was removed





Corresive" was removed HAZARDS TO HUMANS AND DOMESTIC ANIMALS

through skin or inhaled. Do not get in eyes, on skin, or on clothing. Avoid breathing vapor. Wear protective clothing and gloves, and protective eyewear (goggles or face shield). Wash thoroughly with soap and water after handling and before eating, drinking, Causes substantial but temporary eye injury. May be fatal if swallowed. Causes skin irritation. Harmful if absorbed using tobacco, or using the toilet. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in

De-activation of AM 500 I can be achieved by the addition of anionic surfactant in quantity equivalent to that of AM 500 I.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

AM 500 I can be incorporated directly into formulations used to make the end products listed under "approved uses."

AM 500 I can also be diluted by adding 0.2 to 2 fluid ounces AM 500 I per cup (3.2 to 32 fluid ounces AM 500 I per gallon) of water padding, soaking, spraying, fogging or by using foam finishing techniques to give a final treatment of 0.1 to 1.0 percent by weight or other solvents (for example, alcohol and ketones) and then applied to organic or inorganic substrates by brushing, dipping, active ingredient. After applying the antimicrobial agent, the substrate can then be dried at temperatures from ambient to a maximum of 160° C (320° Optimum application and drying conditions, such as time and temperature, should be determined for each application before use. F) to effect complete condensation of silanol groups and to remove water, solvents and/or traces of methanol from hydrolysis.

"... listed in the attached Information... was deteted For formulating use into end-use products.

was detered "Note: This product should not be used....

"disinfectants" santizers" of air treatment products The words

AM 500 l is approved for use in formulating microbiocides for use in laundry additives, carpet treatment products, upholstery and drapery treatment products, and building cleaning and treatment products.

The active ingredient in AM 500 Lis effective against fungi (including mold and mildew), algae, and yeasts

AM 500 I can be used for incorporation into and treatment of the following items or substrates to impart durable antimicrobial protection:

- Air filters for furnaces, air-conditioners, air purification devices, automobiles, recirculating air handling systems;
- Air filters/materials;
- Aquarium filter material:
- Bed sheets, blankets, and bedspreads;
- Buffer pads (abrasive and polishing); Carpets and draperies;
- Fiberglass ductboard;
- Fiberfill for upholstery, sleeping bags, apparel, etc., where the fiber is cotton, natural down, nylon, polyester, rayon, or wool;
- Fire hose fabric;
- Humidifier belts:
- Mattress pads and ticking;
- Men's underwear and outerwear;

building materials

USES alebered:

pool + spa filters

an fiber uses

Concrete...

- Non-woven disposable diapers:
 - Non-woven polyester;
- Outerwear apparel;
- Disposable polyurethane foam cushions for Lapidus Airfloat Systems;
- Polyurethane foam for household, industrial, and institutional sponges and mops;
 - Polyurethane and polyethylene foam, when covered;
- Polyurethane foam for packaging and cushioning in non-food contact applications;
- Polyurethane foam used as a growth medium for non-food crops and plants;
- Pre-moistened towelettes and tissue wipes (these do not impart pesticidal properties);
- Roofing materials defined as shingles, roofing granules, wood shakes, felt, stone and synthetic overcoats;
 - Sand bags, tents, tarpaulins, sails, and ropes;
 - Athletic and casual shoes;
- Shoe insoles;
- Shower curtains;
- Socks comprised of nylon, nylon/orlon, cotton/nylon, linen/Lycra, acrylic/polypropylene/nylon/Lycra, wool/silk/nylon/Lycra and wool/acrylic/nylon/Lycra;
- Throw rugs;
- Toweling made of 100 percent cotton, 100 percent polyester, and blends of the two fibers;
- Toilet tank and seat covers;

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- Upholstery made of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polyolefins, polypropylene, rayon, spandex, vinyl,
- Vacuum cleaner bags and filters;





































- Vinyl paper-wallpaper for non-food contact surfaces;
- Disposable wiping cloths that can be used for multiple purposes such as dusting or washing furniture, cars, walls, windows, floors, appliances, dishes, counter tops, etc.; the wiping cloths do not impart pesticide properties;
 - Women's hosiery; and
- Women's intimate apparel.

EPA REGISTRATION REQUIREMENTS

The applications for which this product is used may require approval by the Environmental Protection Agency on an end-use basis in regard to claims made thereof. Formulators are responsible for satisfying registration requirements for their products.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

inaccessible to children and away from food or feed. AM 500 I has a minimum shelf life of 12 months from the date of shipment Pesticide Storage: Store in original, tightly closed containers below 30°C (86°F) and above 0°C (32°F) in a secure area from BioShield.

violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

FOR MORE INFORMATION CONCERNING THIS PRODUCT, PLEASE CONSULT THE MATERIAL SAFETY DATA SHEET (MSDS). THE MSDS CAN BE OBTAINED BY WRITING BIOSHIELD TECHNOLOGIES, INC. AT 4405 INTERNATIONAL BOULEVARD, SUITE B109, NORCROSS, GEORGIA, 30093.

IMPORTANT: WARRANTY AND DISCLAIMER INFORMATION

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BioShield Technologies, Inc., warrants that the product conforms to its chemical description and is reasonably fit for the purposes stated in this bulletin when used in accordance with directions under normal conditions of use; but this warranty of fitness for a particular purpose does not extend to the use of this product contrary to bulletin instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to seller, and buyer assumes the risk of any such use. BIOSHIELD SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING THE WARRANTY OF MERCHANTABILITY.

COLLATERAL LABELING

BioShield Technologies, Inc.

4405 International Boulevard, Suite B109 Norcross, GA 30093

cleaning and treatment products to give a surface-durable antimicrobial treatment

Information About Antimicrobial Agents

TYPICAL PROPERTIES

These values are not intended for use in preparing specifications

	CH ₃
Structure	[(CH ₂ O) ₂ Si(CH ₂) ₂ N=C ₄ ₂ H ₂ z ¹ C ₁
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Concentration	CH ₃
Appearance	
Solubility	
Thermal Stability °C (°F)	Stable to 30°C (86°F)

DESCRIPTION

AM 500 I is BioShield's designation for 3-(trimethoxysilyI) propyloctadecyldimethyl ammonium chloride containing 5 percent active ingredient by weight. Alkoxysilanes of this nature have been shown to form durable bonded coatings to a number of materials (see "References" section).

AM 500 I offers users the following features:



- Good durability—BIOSHIELD AM 500 I Antimicrobial Agent imparts durable biostatic activity to the surface of a wide variety of substrates; it is leach-resistant and nonmigrating and is not consumed by microorganisms.
- Increased efficiency—through proper application, durable bacteriostatic, fungistatic and algistatic surfaces can be attained with a minimum amount of AM 500 I.

BENEFITS

The following benefits are derived when a formulation containing the active ingredient is applied to a surface:

- Provides hygienic freshness and combats deterioration caused by bacteria, fungi, algae, and yeasts.
- Inhibits growth of bacteria and mildew on the treated article.
- Prolongs the life of a article by inhibiting the growth of bacteria and mildew.
- Resists development of bacterial and fungal odors.
- Retains freshness by resisting the growth of odor-causing bacteria and mildew (fungus).
- Provides a chemical treatment that enables fabrics to resist odors.
- Provides a unique chemical treatment that resists mildew and bacteria growth and imparts odor resistance.
- Product performance with little degradation up to 375°F.

Materials treated with formulations containing the antimicrobial agent AM 500 I are preserved by the bacteriostatic, fungistatic and algistatic action imparted by the active ingredient. AM 500 I inhibits the growth of microorganisms that are responsible for causing odor, discoloration and deterioration. It also provides residual inhibition of microorganisms to aid in the control of these deleterious effects. AM 500 I forms a coating on a wide variety of substrates and antimicrobial action is exhibited on contact.

APPROVED USES



AM 500 I is approved for use in formulating microbiocides for use in laundry additives, carpet treatment products, upholstery and drapery treatment products, and building cleaning and treatment products.

*

The active ingredient in AM 500 I is effective against fungi (including mold and mildew), algae, and yeasts.



AM 500 I can be used for incorporation into and treatment of the following items or substrates to impart durable antimicrobial protection:

- Air filters for furnaces, air-conditioners, air purification devices, automobiles, recirculating air handling systems;
- Air filters/materials;
- Aguarium filter material;
- Bed sheets, blankets, and bedspreads;
- Buffer pads (abrasive and polishing);
- Carpets and draperies;
- Fiberfill for upholstery, sleeping bags, apparel, etc., where the fiber is cotton, natural down, nylon, polyester, rayon, or wool;
- Fiberglass ductboard;
- Fire hose fabric;
- Humidifier belts;
- Mattress pads and ticking;
- Men's underwear and outerwear;
- Non-woven disposable diapers;
- Non-woven polyester;
- Outerwear apparel;
- Disposable polyurethane foam cushions for Lapidus Airfloat Systems;
- Polyurethane foam for household, industrial, and institutional sponges and mops;
- Polyurethane and polyethylene foam, when covered;
- Polyurethane foam for packaging and cushioning in non-food contact applications;
- Polyurethane foam used as a growth medium for non-food crops and plants;
- Pre-moistened towelettes and tissue wipes (these do not impart pesticidal properties);
- Roofing materials defined as shingles, roofing granules, wood shakes, felt, stone and synthetic overcoats;
- Sand bags, tents, tarpaulins, sails, and ropes;
- Athletic and casual shoes;
- Shoe insoles:
- Shower curtains;
- Socks comprised of nylon, nylon/orlon, cotton/nylon, linen/Lycra, acrylic/polypropylene/nylon/Lycra, wool/silk/nylon/Lycra and wool/acrylic/nylon/Lycra;
- Throw rugs:
- Toweling made of 100 percent cotton, 100 percent polyester, and blends of the two fibers;
- Toilet tank and seat covers;
- Umbrellas:
- Upholstery made of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polyolefins, polypropylene, rayon, spandex, vinyl, and wool;
- · Vacuum cleaner bags and filters;
- Vinyl paper-wallpaper for non-food contact surfaces;
- Disposable wiping cloths that can be used for multiple purposes such as dusting or washing furniture, cars, walls, windows, floors, appliances, dishes, counter tops, etc.; the wiping cloths do not impart pesticide properties;
- Women's hosiery; and
- Women's intimate apparel.

DIRECTIONS FOR USE

AM 500 I can be incorporated directly into formulations used to make the end products listed in this bulletin.

AM 500 I can be diluted by adding 0.2 to 2 fluid ounces of AM 500 I per cup (3.2 to 32 fluid ounces of AM 500 I per gallon) of water or other solvents (for example, alcohol, and ketones) and then applied to organic or inorganic substrates by brushing, dipping, padding, soaking, spraying, fogging or by using foam finishing techniques to give a final treatment of 0.1 to 1.0 percent by weight active ingredient.

After applying the antimicrobial agent, the substrate can then be dried at temperatures from ambient to a maximum of 160° C (320° F) to effect complete condensation of silanol groups and to remove water, solvents and/or traces of methanol from hydrolysis. Optimum application and drying conditions, such as time and temperature, should be determined for each application before use.

PRECAUTIONARY STATEMENTS

Warning. Causes substantial but temporary eye injury. May be fatal if swallowed. Causes skin irritation. Harmful if absorbed through skin or inhaled. Do not get in eyes, on skin, or on clothing. Avoid breathing vapor. Wear protective clothing and gloves, and protective eyewear (goggles or face shield). Wash thoroughly with soap and water after handling and before eating, drinking, using tobacco, or using the toilet. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

Inactivation of solutions containing AM 500 I may be accomplished by one of the following methods:

- addition of an anionic surfactant or detergent in quantity equivalent to that of AM 500 I in solution; or
- addition of Triton X-100 nonionic detergent at a final concentration of 10,000 ppm (1.0 percent volume/volume) or greater to bath solutions up to 1.0 percent volume/volume of AM 500 I.

Every effort should be made to contain accidental spills of AM 500 I to the immediate area. This may be accomplished by the use of sandbags to confine the spill to facilitate cleanup and disposal. Contaminated sand may then be disposed of by burial in an approved landfill. Many spills may be cleaned up with rags by wiping and/or mopping and allowing the liquid to absorb into the fabric. The rags may then be disposed of by incineration.

Floor drains in areas of material use should be protected with sandbags to contain accidental spills.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in original, unopened containers below 3°C (86°F) and above 0°C (32°F). AM 500 I has a minimum shelf life of 12 months from the date of shipment from BioShield.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Before handling, read product label in its entirety

IMPORTANT: WARRANTY AND DISCLAIMER INFORMATION

BioShield Technologies, Inc., warrants that the product conforms to its chemical description and is reasonably fit for the purposes stated in this bulletin when used in accordance with directions under normal conditions of use; but this warranty of fitness for a particular purpose does not extend to the use of this product contrary to bulletin instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to seller, and buyer assumes the risk of any such use.

BIOSHIELD SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING THE WARRANTY OF MERCHANTABILITY.

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BioShield Technologies, Inc. 4405 International Boulevard, Suite B109 Norcross, GA 30093

FQPA,

DP BARCODE: D246364

CASE: 061695 UBMISSION: S543103 DATA PACKAGE RECORD

BEAN SHEET

DATE: 05/2 Page 1 of

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 187 RESB AMD-OC-MINOR CHG

CHEMICALS: 107401 3-(Trimethoxysilyl) propyl dimethyl octadecyl ammon 5.0000%

ID#: 070871-E BIOSHIELD AM 500 I

COMPANY: 070871 BIOSHIELD TECHNOLOGIES, INC

PRODUCT MANAGER: 31 VELMA NOBLE 703-308-6233 ROOM: CS1 6W18
PM TEAM REVIEWER: TRACY LANTZ 703-308-6415 ROOM: CS1 6W5

RECEIVED DATE: 05/07/98 DUE OUT DATE: 09/04/98

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 246364 EXPEDITE: N DATE SENT: 05/27/98 DATE RET.: / / CHEMICAL: 107401 3-(Trimethoxysilyl)propyl dimethyl octadecyl ammonium chlor

OP TYPE: 001

CSF: N LABEL: Y

ASSIGNED TO
DIV : AD
BRAN: EASSB
SECT: CTT
REVR : JB

CONTR:

DATE IN 5/7/98 5/27/98 DATE OUT

ADMIN DUE DATE: 08/30/98

NEGOT DATE: / /
PROJ DATE: / /

* * * DATA REVIEW INSTRUCTIONS * * *

Karen, please review for Acute Tox., registrants submission of a primary eye irritation study, # 44553501
Thank You!

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC BRANCH/SECTION DATE OUT DUE BACK INS CSF LABEL

NOTE TO THE JACKET

70871-R

and

70871-E

9/4/98

Note: BioShield is

The proposed products (70871-R and -E) contain 5% A.I. Dow Corning 5700 (64881-1) contains the same A.I. at 42% plus methanol.

The following are the Tox reviews which have been done for these products or are relevant because they refer to studies which the may be cited for these products.

1) Acute Inhalation

Ian's review of 8/31/98 is an addendum to his 8/7/98 review.

In the latter review he was willing to infer

Tox category for acute inhalation. Both were registered without the submission of an acute inhalation study.

The acute inhalation study which was mentioned by the applicant as part of the "existing data" (MRID 41157803) had a cursory review by Wallace on 1/13/98 and was found to be unacceptable. This review was previously sent to the applicant in reference to 70871-G in our letter dated 1/13/98. Thus they should already realize that there are problems with this active ingredient in terms of acute inhalation.

Therefore Dennis, Velma, and myself were uncomfortable registering these products without a relevant acute inhalation study.

2) Dermal Sensitization

In his review of 8/31/98 Ian denied their waiver and recommended that a dermal sensitization study be submitted.

The applicant stated as "existing data" a skin sensitization study on Dow Corning 5700 (MRID 42197401).

This study (MRID 42197401) was reviewed by Wallace on 1/13/98 for 70871-G and he felt that it indicated no sensitization for the concentrated material and thus was acceptable on a tentative basic. Since Dow Corning 5700 is 42% A.I. plus methanol (which would supposedly make it more irritating) and the proposed product is only 5% A.I. we, Dennis Velma and I, are willing to let the applicant cite this study to satisfy the requirement for dermal sensitization.

A copy of Wallace's review of 1/13/98 was included in the correspondence to the applicant.

3) Efficacy Claims

I conferred with both Walter and Srivinas in terms of the efficacy claims on these labels. See my notes on the label marked "my copy." Also included is the memo sent out by Walter explaining the use of the terms "antimicrobial" and "antibacterial" on non public health products.

Tracy Lantz

Trong Tang

Team 31



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

August 31, 1998

MEMORANDUM:

Subject:

Acute Toxicity Review for

EPA Reg. No.: DP Barcode:

70871-R D246360

70871-E D246364

Case No:

061691

061695

To:

Velma Noble, PM31 / Tracy Lantz

Regulatory Management Branch Antimicrobials Division (7510W) Im Blackvell

From:

Ian Blackwell, Biologist

Efficacy Evaluation Team

Efficacy and Science Support Branch Antimicrobials Division (7510W)

Applicant:

Bioshield Technologies, Inc.

FORMULATION FROM LABEL:

Active Ingredient(s): 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride Other Ingredient(s):

% by wt. 5 95

Total:

100%

BACKGROUND: This is an addendum to an 8/7/98 ESSB review of file symbols 70871-R and 70871-E. In that review the acute toxicity profile for these two products was:

acute oral toxicity	IV	acceptable
acute dermal toxicity	Ш	acceptable
acute inhalation toxicity		unknown
primary eye irritation	II	acceptable
primary skin irritation	Ш	acceptable
dermal sensitization		unknown

Since that review, ESSB has been presented with additional reviews and registrant letters that were not in the previous submission.

RECOMMENDATIONS:

As a result of the additional information the acute toxicity profile for 70871-R and -E is:

acute oral toxicity	IV	acceptable
acute dermal toxicity	Ш	acceptable
acute inhalation toxicity	Ш	cited (see 1 below)
primary eye irritation	II	acceptable
primary skin irritation	III	acceptable
dermal sensitization		unknown ² (see 2 below)

- This information is inferred from the product label of reg. no.
 which is the source of the active ingredient used in file symbols 70871-R and -E. No acute toxicity profile could be found for reg. no.
- 2. A 5/14/97 letter requests a waiver of the six acute toxicity studies. This reviewer assumes that this is because reg. no. is labeled as being a corrosive product. Typically, if a product is dermally corrosive, the dermal sensitization study is waived because the user is to avoid all dermal contact with this product. (Dermal contact is avoid because the product has the potential to burn or severely irritate the skin.) However, the same registrant letter lists a dermal sensitization study and MRID number. The study listed was conducted on another product with the same active ingredient but a very different overall composition. Unless it is positive for dermal sensitization, that study (MRID number 421974-01) will not be sufficient to support this product.

It is noted, however, that while reg. no. ______is listed as being corrosive, file symbols 70871-R and -E are not. Thus, file symbols 70871-R and -E do not have the scientific support for a waiver for a dermal sensitization study. ESSB recommends that a dermal sensitization study be conducted to support file symbols 70871-R and -E.

LABELING:

Date: 08/31/98

LABEL REVIEW SYSTEM

Page: 1

ID #: 070871-00002 BIOSHIELD AM 500 I

SIGNAL WORD: WARNING

PRECAUTIONARY STATEMENTS:

Causes substantial but temporary eye injury. Harmful if absorbed through skin or inhaled. Do not get in eyes or on clothing. Avoid contact with skin. Avoid breathing spray mist. Wear goggles or face shield. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

STATEMENT OF PRACTICAL TREATMENT (SOPT):

IF SWALLOWED: Call a physician or Poison Control Center. Do not induce vomiting. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention. For Category III, add "if symptoms persist."

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

IF IN EYES: Hold eyelids open and flush with steady, gentle stream of water for 15 minutes. Get medical attention.

Probable mucosal damage may contraindicate the use of gastric lavage.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

August 7, 1998

MEMORANDUM:

Subject:

Acute Toxicity Review for

EPA Reg. No.:

70871-R

70871-E

DP Barcode:

D246360

D246364

Case No:

061691

061695

To:

Velma Noble, PM31 / Tracy Lantz

Regulatory Management Branch Antimicrobials Division (7510W)

From:

Ian Blackwell, Biologist

Efficacy Evaluation Team

Im Blackwell Efficacy and Science Support Branch Antimicrobials Division (7510W)

Through:

Karen Hicks, Acting Team Leader

Toxicology and Chemistry Team

Efficacy and Science Support Branch

Antimicrobials Division (7510W)

Applicant:

Bioshield Technologies, Inc.

FORMULATION FROM LABEL:

Active Ingredient(s): 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride

Other Ingredient(s):

% by wt. 5

95

Total:

100%

<u>BACKGROUND</u>: Bioshield Technologies has submitted a primary eye irritation study to support "Bioshield AM 500" and "Bioshield AM 500 I." The study was conducted by Stillmeadow, Inc. The MRID number is 445535-01.

RECOMMENDATIONS: ESSB findings are:

The primary eye irritation study is acceptable to support both registration numbers 70871-R and 70871-E.

The acute toxicity profile for reg. nos. 70871-E and 70871-R are currently:

acute oral toxicity	IV	acceptable
acute dermal toxicity	III^1	acceptable
acute inhalation toxicity	2	
primary eye irritation	Π_1	acceptable
primary skin irritation	III^1	acceptable
dermal sensitization	2	

Notes:

- 1. The results of the studies other than the primary eye irritation study were derived from a previous AD/RSSB review.
- 2. ESSB was unable to find any reviews of acute inhalation toxicity or dermal sensitization studies submitted for these products. See Wallace Powell's review of 9/2 97

LABELING:

No precautionary labeling can be recommended until the fulfillment of the requirement for the acute inhalation toxicity and dermal sensitization studies.

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4, 870.2400)

Product Manager: 31

Reviewer: Ian Blackwell

MRID No.: 445535-01

Study Completion Date: 4/28/98

Report No.: 4263-98

Testing Laboratory: Stillmeadow, Inc.

Author(s): Janice O. Kuhn, PhD

Quality Assurance (40 CFR §160.12): Included

Test Material: AM500; "yellow gel"

Dosage: 0.1 mL

Species: New Zealand White albino rabbits

Sex: 3 males + 3 females

Weight: males = 2.475-2.900; females = 2.775-3.000

Age: young adult

Source: Ray Nichols Rabbitry

Summary:

1. Toxicity Category: ΙΙ

2. Classification:

acceptable

Procedure (Deviations From §81-4): none

Results:

		(nu	mber "j	positive	''/numb	er teste	ed)	
Observations	Hour		Days					
	1	1	2	3	4	7	10	21
Corneal Opacity	2/6	1/6	1/6	1/6	1/6	0/6	0/6	-~-
Iritis	2/6	0/6	0/6	0/6	0/6	0/6	0/6	
Conjunctivae								
Redness	6/6	6/6	5/6	3/6	3/6	1/6	0/6	
Chemosis	0/6	3/6	2/6	2/6	2/6	0/6	0/6	
Discharge	6/6	2/6	2/6	2/6	2/6	0/6	0/6	

Stippling was observed in 4/6 animals at one hour.

Iritial constriction was observed in 2/6 animals through day 4.

Ocular blanching was observed in 2/6 animals through day 4 and 1/6 through day 7.

--- = no observations at this point

Viena copy

Bioshield Technologies, Inc. 4405 International, Suite B109 Norcross, GA 30093

10H 1 3 1998

Subject: BST Protectant Concentrate C15

EPA File Symbol No. 70871-G

Your Submission Dated September 12, 1997

Attn: Blane Dahl

Registration Manager

The application for registration of the subject product is not acceptable. Required materials as specified below must be submitted before processing of the application can be completed.

Product Chemistry

The Confidential Statement of Formula (CSF) dated September 12, 1997 is in compliance with PR Notice 91-2, it agrees with the label and is acceptable. The product chemistry data in MRID Nos. 443760-01, 443760-02 and 443760-03 provides data for Guideline Reference Series 61, 62 and 63. This data is in compliance with 4 CFR part 158.155-158.190 and it satisfies product chemistry data for this product except for Guideline Reference No. 63-17 Storage and Stability. Please submit one year Storage and Stability data to support claim "Disinfects up to one year".

The claim "Contains no phenols, tin, heavy metals, lead, mecury or formaldehyde" is not acceptable and must be deleted. All other claims will be re-evaluated when additional data is forwarded to the Agency.

Efficacy

Data submitted is insuffient. Agency need appropriate data to support the label claims. Please send in sufficient material to be re-evaluated.

Toxicity Review

Please refer to the Attachment entitled "Memorandum" for comments.

Because of the importance of your application, we would like to have your reply within seventy-five (75) days. If you need additional time to reply or if you have any questions concerning the comments in this letter, you may contact Zenobia Jones at (703) 308-6198.

Sincerely,

Velma Noble

Product Manager 31

Regulatory Management Branch 1 Antimicrobial Division (7510W)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND **TOXIC SUBSTANCES**

JAN | 3 | **1998**

MEMORANDUM

Subject:

BST Protectant Concentrate C15

EPA File Symbol 70871-G Data Package D239768

BST Protectant 50

EPA File Symbol 70871-U Data Package D239765

BST Protectant 75

EPA File Symbol 70871-L Data Package 0239760

From:

Wallace Powell, Biologist 4

Risk Assessment and Science Support Branch

Antimicrobials Division (7510W)

Thru:

Laura E. Morris, Team Leader

Risk Assessment and Science Support Branch

Antimicrobials Division (7510W)

Norman Cook, Chief

m/ Cuc 01/13/58 Risk Assessment and Science Support Branch

Antimicrobials Division (7510W)

To:

Velma Noble, Product Manager, Team 31

Zenobia Jones, Team Reviewer, Team 31

Registration Branch I Antimicrobials Division

BACKGROUND

The applicant, BioShield Technologies, Inc. (as represented by Jellinek, Schwartz & Connolly, Inc.), has applied for registration of BST Protectant Concentrate C15, BST Protectant 50, and BST Protectant 75, three manufacturing-use products proposed for incorporation into anti-microbial products that are used in cleaning products, textile and building treatment products, and a variety of manufactured items. The applicant has submitted a request for waivers of all product acute toxicity testing, and has cited several studies to show that existing data are sufficient to support registration.

DISCUSSION

According to a December 4, 1997 EPA memorandum from Timothy McMahon to Velma Noble, the following data is available for the active ingredient contained in these products. The memorandum notes that these tests were conducted on a 50% formulation.

Study Type	MRID No.	Tox. Category
Acute Oral Toxicity	403852-01	IV
Acute Dermal Toxicity	403852-01	III
Primary Eye Irritation	403852-01	I
Primary Dermal Irritation	403852-01	III

The subject products are water dilutions of a product resembling the product for which the studies cited in this memorandum were submitted. The dilution factors are rather large.

In support of registration of the subject products, the applicant has cited the above MRID 403852-01 and several additional studies also: 424565-11 (acute oral toxicity), 432199-01 (acute dermal toxicity), 411578-03 (acute inhalation toxicity), 932180-47 and 424565-13 (primary dermal irritation), and 421974-01 (dermal sensitization). Of these, according to our records, the acute oral toxicity study, MRID 424565-11, has been reviewed previously with a Toxicity Category IV result ($LD_{50}=12.27~g/kg$), which is in agreement with the result in the list above. Because this is the Category of lowest toxicity, Category IV can be assigned to the subject products.

The acute dermal toxicity study with MRID No. 432199-01 is also not being reviewed for this memorandum. The study listed above with MRID No. 403852-01 was assigned Category III for acute dermal toxicity, and this Category can be assigned to the subject products for labeling purposes.

Based on a cursory review of the acute inhalation study, MRID No. 411578-03, the number and spacing of the dose concentrations were not appropriate for the calculation of an LC_{50} . Two dose concentrations were used (both within the Toxicity Category II

range). There was no third concentration, and there was no mortality which could be used for calculating an LC₅₀. The study is therefore not acceptable. An acceptable acute inhalation study is required, as conducted on the subject product formulations, as represented by BST Protectant Concentrate C15 (since its concentration is the highest of the three products).

As for primary eye irritation, Toxicity Category I is listed above for the concentrated material, but it is not known what Toxicity Category would result from the dilution represented by the subject products. Therefore an acceptable eye irritation study is required, as conducted on the subject product formulation. To reflect the source material's Category I rating for eye irritation in the BioShield products may result in a significant overstatement of the hazard.

As for the primary dermal irritation studies with MRID Nos. 932180-47 and 424565-13, based on a cursory review of the studies it was noticed that individual animal data was not included, and observations ended at 72 hours in spite of the presence of significant irritation. The two studies suggest a Toxicity Category of I or II for primary dermal irritation. This is not in agreement with the Category III indicated for the MRID 403852-01 study listed above. Thus, the dermal irritation assessment is inconclusive, and a study is required for the diluted material.

The cited dermal sensitization study, MRID No. 421974-01, appears acceptable based on cursory review, indicating no sensitization response for the concentrated material. Therefore, the study is applicable to the subject product as well, acceptable on a tentative basis, until a complete review is conducted in the reregistration process. (It is this reviewer's intention to provide a review report well prior to that time.)

CONCLUSION

As per the foregoing discussion, the following Toxicity Categories can be assigned to the subject product for purposes of determining appropriate precautionary labeling.

Note that if the outcomes of the evaluations as a part of the Reregistration process (which are not yet completed) differ from these Toxicity Categories listed below, new data will be required.

Acute Effect

Acute Oral Toxicity

Acute Dermal Toxicity

Acute Inhalation Toxicity

Primary Eye Irritation

Primary Dermal Irritation

Dermal Sensitization

Category

IV

III (assigned)

Study is required -

Study is required

Study is required

Non-sensitizer (tentative)

The precautionary labeling requirements for the subject product will be determined once the acute toxicity data requirements have been fulfilled.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

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DEC - 4 1997

Cur 12/04/97

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: 3-(Trimethoxysilyl) propyl dimethyl octadecyl ammonium

chloride: review of a data waiver request

EPA Identification Numbers:

P.C. Code: 107401 DP Barcode: D239858 Submissions: S531642

MRID: N/A

TO: Velma Noble / Julie Fairfax

PM Team # 31

Regulatory Management Branch I Antimicrobials Division (7510W)

FROM: Timothy F. McMahon, Ph.D.

Senior Toxicologist, RASSB

Antimicrobials Division (7510W)

THRU: Winston Dang, Ph.D.

Acting Leader, Team One

RASSB/AD (7510W)

and

Norm Cook Chief, RASSB

Antimicrobials Division (7510W)

Registrant: BioShield Technologies, Inc.

Action Requested: Review of available acute toxicity data for 3-(trimethoxysilyl) propyl dimethyl octadecyl ammonium chloride in support of data waiver requests for BST Mold and Mildew Remover and All Purpose Cleaner 25.

Product ingredient source information may be entitled to confidential treatment

Manufacturing process information may be entitled to confidential treatment

BST Mold and Mildew Remover waiver request

2

Background

The registrant (BioShield Technologies, Inc.) has submitted a request for waiver of conduct of acute toxicity studies for the formulation BST Mold and Mildew Remover, containing the active ingredient 3-(trimethoxysilyl) propyl dimethyl octadecyl ammonium chloride at a concentration of 0.25%. The registrant claims that this formulation is a dilution of

The following Toxicology data is available in support of this active ingredient. It is noted that the acute toxicity tests were performed on a 50% formulation:

3-(Trimethoxysilyl)propyl dimethyl octadecyl ammonium chloride (non-food)

Study Type	MRID No.	1.2	Re	equired	4	Sat	isfied
Acute Oral	40385201	 1	. 3	Y		Y	(Cat. IV)
Ć (1 t)		1 1+1					. 11 12 121
Acute Dermal	40385201		- T	Y		. Y	(Cat. III)
.		£				÷	18
Acute Inhalation	41157803	2 .	-	Y		N	(Cat. II)
		ŧ.		1.0		11114	# 7
Primary Eye Irr.	40385201			Y		Y	(Cat. I)
				Y			
Primary Dermal Irr.	40385201		- 1	Y		Y	(Cat. III)
Dermal Sensitizatio	n	Ĵ.	1	Y	E		N .

Reccomendations:

The Risk Assessment and Science Support Branch (RASSB), Antimicrobials Division (AD), has examined the request from the registrant for waiver of acute toxicity testing of BST Mold and Mildew Remover based on data available for the same active ingredient at a higher concentration.

RASSB concludes that:

- 1) Of the studies cited by the registrant, several appear to have not been reviewed by the Agency. Specifically, MRID No's 42456511, 43219901, 42456513, and 42197401. If the registrant has knowledge that these studies were reviewed, these data should be provided to the Antimicrobials Division.
- 2) The registrant has employed the signal word "Caution" on the proposed label for BST Mold and Mildew Remover, but there are no product specific data to suport this claim. It is understood that the product represents a significant dilution of the active ingredient, but for many quaternary amonium compounds, Category I labeling statements have been applied even at low concentrations. The registrant should accept Category I labeling for the product or generate product specific acute toxicity data for primary eye irritation and primary dermal irritation, as these were the studies, upon which the Category I labeling statements would be based.
- 3) It is noted that for a non-food use of this active ingredient, the following data gaps appear to exist and are required, based on a review of the available data for 3-(Trimethoxysily1)propyl dimethyl octadecyl ammonium chloride: an acceptable dermal sensitization test; an acceptable subchronic toxicity test; an acceptable developmental toxicity test; acceptable mutagenicity tests (the only acceptable mutagenicity test on file os listed as MRID # 41296803, mouse micronucleus assay). If the registrant has information to support data requirements in these areas, these data should be submitted to Antimicrobials Division. The registrant should also be aware of the proposed Subpart W, Part 158, Antimicrobial Data Requirements, in which immunotoxicity testing and neurotoxicity testing requirements exist for non-food uses of antimicrobial pesticides.

JAN 2 | 1998

BioShield Technologies, Inc. c/o Jellinek, Schwartz & Connolly, Inc. 1525 Wilson Boulevard, Suite 600 Arlington, VA 22209

Attn: Blane Dahl

Agent for Bioshield

Subject: Application for Registration

BST Mold and Mildew Remover & All Purpose Cleaner 25

EPA File Symbol 70871-RR

Your Submission Dated September 19, 1997

The application referred to above has been determined pursuant to 40 CFR 152.104 (53 FR 15980, May 4, 1988) not to be sufficiently complete to process; therefore, the application is considered deficient. Labeling/other information specified below must be submitted before processing of the application can be completed.

1. The request for waiver of acute toxicity testing of this product, based on data available for the same active ingredient at a higher concentration, has been examined with the following conclusions:

Of the studies cited by the registrant several appear to have not been reviewed by the Agency. Specifically, MRID No's 42456511, 43219901, 42456513, and 42197401. If you have knowledge that these studies have been reviewed, please provide the reviews to the Antimicrobials Division.

- 2. You have used the signal word "Caution" on the proposed label for this product, but there are no product specific data to support this claim. It is understood that this product represents a significant dilution of the active ingredient, but for many quaternary ammonium compounds, Category I labeling statements have been applied even at low concentrations. You should accept Category I labeling for the product or generate product specific acute toxicity data for primary eye irritation and primary dermal irritation, as these were the studies upon which the Category I labeling statements would be based.
- 3. It is noted that for a non-food use of this active ingredient, the following data gaps appear to exist and are required: an acceptable dermal sensitization test, an acceptable subchronic toxicity test, an acceptable developmental toxicity test, and acceptable mutagenicity tests. If you have information to support these data requirements, please submit this to the Antimicrobials Division. Also note that in the proposed Subpart W, Part 158, Antimicrobial Data Requirements, 7510W:J.Fairfax:1/7/98:70871-RR

immunotoxicity testing and neurotoxicity testing requirements exist for non-food uses of antimicrobial pesticides.

- 4. The submitted product chemistry data is adequate and supports the registration requirements for this product. The analytical methods were also reviewed and found acceptable.
- 5. The Confidential Statement of Formula (CSF) dated September 19, 1997 is not acceptable. You must submit additional information on two of your inert ingredients. Specifically, please ask your suppliers of submit the following information to the Agency: 1) chemical names, 2)CAS #'s, and 3) percent of each component in the inert. These inerts are not cleared for use in pesticide formulations.
- 6. Since you are making public health claims on the proposed product labeling for BST Mold and Mildew Remover & All Purpose Cleaner 25, the Agency requires you to submit efficacy data to support the proposed labeling claims.

If you have any questions concerning this letter, please contact Julie Fairfax at (703) 308-9086.

Sincerely yours,

Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510W)

Product ingredient source information may be entitled to confidential treatment



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

9/2/97

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Subject:

BioShield AM 500 I, EPA File Symbol 70871-E

Data Package D236250

BioShield AM 500, EPA File Symbol 70871-R

Data Package D236249

From:

Wallace Powell, Biologist

Risk Assessment and Science Support Branch

Antimicrobials Division (7510W)

Thru:

Laura E. Morris, Acting Team Leader When W. Vaux

Risk Assessment and Science Support Branch og

Antimicrobials Division (7510W)

09/03/97 Norman Cook, Chief

Risk Assessment and Science Support Branch

Antimicrobials Division (7510W)

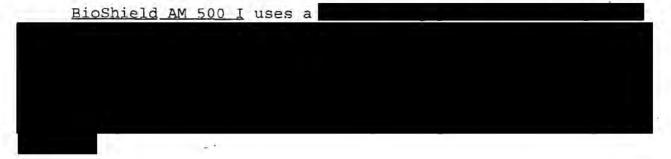
To:

Velma Noble, Product Manager, Team 31 Barbara Pringle, Team Reviewer, Team 31

Registration Branch I Antimicrobials Division

BACKGROUND

The applicant, BioShield Technologies, Inc. (as represented by Jellinek, Schwartz & Connolly, Inc.), for registration of the two subject products has submitted a request for waivers of all product acute toxicity testing. These two products are identical in composition - BioShield AM 500 (EPA File Symbol 70871-R) is a 100% repackaging of BioShield AM 500 I (EPA File Symbol 70871-E).



CONTAINS CONFIDENTIAL BUSINESS INFORMATION

Product ingredient source information may be entitled to confidential treatment

Manufacturing process information may be entitled to confidential treatment



The applicant has cited several acute toxicity studies, submitted for the Dow Corning material during the years 1987 through 1994, claiming that EPA accepted these studies when it registered the Dow Corning product. (The studies with MRID Numbers 001285-46 through -49 appear to be the ones on which initial registration was based; the studies cited now by the applicant may or may not include re-submissions of those older studies.)

No Reregistration Eligibility Decision (RED) document has yet been issued for the active ingredient in these products, which is assigned to Reregistration Case 3148, Trimethoxysilyl Quats.

RECOMMENDATION



With the exception of the statements reflecting eye irritation hazard in the "Hazards to Humans and Domestic Animals" paragraph, the <u>BioShield AM 500 I</u> and <u>BioShield AM 500 label</u> statements would appear acceptable if based on the Reg. No.

In terms of current labeling guidelines, the precautionary statements are not entirely consistent with the acute toxicity categories which were assigned to its source material, Reg. No.

at the time of the source material's registration. However, it is recommended that this issue be attended to at the time of reregistration of the trimethoxysilyl quats, and that the precautionary statements proposed for the two BioShield products be accepted with the exception of the eye irritation human hazard statements mentioned above.

It is recommended that a primary eye irritation study (guidelines no. 81-4) be required for the BioShield material.

It is not clear that the BioShield material should be in Category I for eye irritation (note that the Material Safety Data Sheet for <u>BioShield AM 500 I</u> mentions that the material caused "slight" irritation in rabbits). No Toxicity Category for eye irritation can be assigned to these products since they represent a significant dilution of the material. To reflect the source material's Category I rating for eye irritation in the BioShield products may result in a significant overstatement of the hazard. It is recommended that the eye irritation study be required in the absence of any further information from the applicant.

Pages 180-181 Product ingredient source information may be entitled to confidential treatment

08/31/98

REFERENCE FILES SYSTEM

PAGE 1

Product Formulation Data

64881-1 DOW CORNING 5700

PC CODE PERCENT

CHEMICAL NAME

107401 42.0000

3-(Trimethoxysilyl)propyl dimethyl octadecyl ammonium chloride

You Jange

*Product ingredient source information may be entitled to confidential treatment?

WAIVER REQUEST OF REQUIREMENT FOR FURTHER TESTING

AM 500 May 14, 1997

Test Type and Guideline Reference Number:

Acute Oral Toxicity	Guideline #81-1
Acute Dermal Toxicity	Guideline #81-2
Acute Inhalation Toxicity	Guideline #81-3
Primary Eye Irritation	Guideline #81-4
Primary Dermal Irritation	Guideline #81-5
Dermal Sensitization	Guideline #81-6

Test Substance: AM 500

BioShield Technologies, Inc.'s (BioShield) AM 500 is an end-use product containing 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride, a silicone quaternary ammonium salt as the active ingredient

AM 500 will be used as an all purpose cleaner and kitchen cleaner, a disinfectant spray, a tub and tile mold and mildew cleaner, a carpet and upholstery cleaner, a toilet bowl cleaner, a laundry additive, and as other products outlined on the proposed product label in Volume II of this submission.

All of the above-mentioned studies have been conducted on DOW Corning 5772. This waiver request pertains to the studies to be conducted solely with AM 500.

Summary

A waiver request for the above six acute toxicity studies on AM 500 is requested based on existing toxicology data on DOW CORNING 5772.

However, BioShield is intending to retain

the existing precautionary statements and the signal word based on the toxicity categories dictated by acute toxicology studies conducted with DOW CORNING 5772.

Basis for Waiver Request:

Existing Data

Acute toxicity studies on DOW CORNING 5772 exist in various animal species. The studies described below represent some of the critical studies conducted with this active ingredient. These studies have been accepted by EPA when it registered DOW CORNING 5772. BioShield has been granted permission by Aegis Environmental Management Inc. to reference these data when writing this Acute Toxicity data waiver. No additional new information on acute toxicity would be generated by conducting these studies again. The following is list of studies that BioShield is referencing:

- MRID 40385201 Hobbs, E. (1973) Acute Toxicologic Properties of Dow Corning Q9-5700: Laboratory Project ID: AD-0003. Unpublished compilation prepared by Dow Corning Corp.
- MRID 42456511, Devries, C.; Siddiqui, W. (1983) Acute Oral Toxicity of DOW CORNING 5772 Antimicrobial Agent: Project X9-6346. Prepared by DOW CORNING CORP.
- MRID 43219901, Devries, C.; Siddiqui, W. (1983) Acute Dermal Toxicity of DOW CORNING X9-6346 (DOW CORNING 5772 Antimicrobial Agent): Lab Project Number 4211-3. Unpublished study prepared by DOW CORNING CORP.
- MRID 41157803, Kolesar, G., Siddiqui, W., Staton, E. (1985) An Acute Aerosol Inhalation Toxicity Study with Dow Corning 5772 compound in Rats: Report No. 1312. Unpublished study prepared by Sow Corning Corp. Study Unacceptable (conducted on 50% AI)

 Time Wallace -> said unacceptable study
- MRID 93218047, Dwane, M. (1990) Dow Corning Corp. An acute Dermal Irritation Study of Dow Corning 5772 Antimicrobial Agent: Project X9-6346. Prepared by DOW CORNING CORP.
- MRID 42456513 Devries, C.; Siddiqui, W. (1983) Phase 3 New Submission: Acute Dermal Irritation Study of Dow Corning 5700 Antimicrobial Agent: Lab Project Number: X9-6346. Unpublished study prepared by Dow Corning corp.
- MRID 42197401 Hoffman, R. (1992) A Skin Sensitization Study of Dow corning 5700 Hydrolysate in Guinea Pigs: Lab Project Number: 1992-10000-36929. Unpublished study prepared by Dow Corning Corp.

Not Reviewed

copy Wallace's review 1/13/98

Jellinek, Schwartz & Connolly, Inc.

JSC

Thought acceptable as non-sensitizer 184



Exposure Potential From Intended Uses

BioShield believes that because the product is the exposure hazards are not high. The product label's strong precautionary language will discourage any use of this product not in accordance with the directions for use. In additon, the product label also outlines the appropriate protective clothing to be used and precautions to be taken during use of AM 500.

Summary

Acute toxicity data of DOW CORNING 5772 on all above-mentioned studies (acute oral toxicity, Guideline #81-1; acute dermal toxicity, Guideline #81-2; acute inhalation toxicity, Guideline #81-3; primary eye irritation, Guideline #81-4; primary dermal irritation, Guideline #81-5; and dermal sensitization, Guideline #81-6) are available at the Agency. In addition, BioShield and Dow Corning have reached an agreement to share these data; therefore, BioShield believes that these studies should satisfy the acute toxicity data requirement for its product. BioShield believes that conducting additional studies is not going to provide new information on toxicity of its product. Therefore, available data on DOW CORNING 5772 at the Agency justifies a waiver of additional acute toxicity studies.

Jellinek, Schwartz & Connolly, Inc.

1525 Wilson Boulevard, Suite 600 Arlington, VA 22209 (703) 527-1650 • Fax: (703) 527-5+77

AN COMPANY



Hand Delivered

May 5, 1998

Ms. Velma Noble (Acting PM 31)
Regulatory Management Branch I
Antimicrobials Division (7510W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

Re: Submission of Labels and a Primary Eye Irritation Study in Response to EPA Letters Dated February 5, 1998
BioShield AM 500 and AM 500 I (EPA File Symbols 70871-R and -E)

Dear Ms. Noble:

On behalf of BioShield Technologies, Inc. (BioShield; 4405 International Boulevard, Suite B109, Norcross, Georgia, 30093), we are submitting revised labels and a primary eye irritation study (EPA Guideline Number 81-4) in support of the pending registrations of BioShield AM 500 and AM 500 I (EPA File Symbols 70871-R and -E, respectively). This submission is in response to two EPA letters dated February 5, 1998, one for each of these products. For both of the proposed products, enclosed are the following materials:

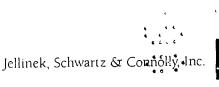
- an 8570-1 form;
- copies of two EPA letters dated February 5, 1998, regarding the registrations of BioShield AM 500 and AM 500 I;
- one copy of proposed product labels submitted on October 15, 1997;
- · one copy of revised, proposed product labels with revisions highlighted;
- five copies of revised, proposed product labels; and
- three copies of a study titled Primary Eye Irritation Study in Rabbits (EPA Guideline No. 81-4).
 44553501

Please note that the revised, draft labeling submitted in this package supersedes the labeling submitted in the package dated April 9, 1998. Also, we have removed all claims on the enclosed draft labels that require the submission of additional efficacy data. BioShield intends to submit efficacy data in the future to support certain antimicrobial claims.

Specific changes made to the proposed BioShield AM 500 and AM 500 I labeling are as follows:

Main Label

- the phrase "Total Ingredients" was added beneath the ingredients statement;
- the signal word was changed from "Danger" to "Warning" and the precautionary language was changed per the current Label Review Manual to reflect the results of the primary eye irritation study (toxicity category II);
- the complete use directions were added to the Directions for Use section (AM 500 I only, AM 500 label already had complete Directions for Use);
- under Directions for Use, the phrase "Note: This product should not be used or compounded with any bleach or oxidizing agents. Do not use in conjunction with anionic surfactants" was deleted;
- under Directions for Use, the phrase "For formulating into end-use products listed in the attached Information About Antimicrobial Agents pamphlet" was shortened to "For formulating into end-use products";
- under Approved Uses, the words "disinfectants" and "sanitizers" and the use "air treatment products" were removed from the first paragraph (AM 500 I only);
- the first paragraph under Approved Uses was revised to read "AM 500 is a
 microbiocide for use in laundry additives, carpet treatment products, upholstery and
 drapery treatment products, and building cleaning and treatment products" (AM
 500 only);
- the phrase "incorporation into and" was removed from the third paragraph under Approved Uses (AM 500 only);
- under Approved Uses, the entire paragraph beginning "<u>Target Pests</u>:..." was deleted;
- the phrase "The active ingredient in AM 500 [I] is effective against fungi (including mold and mildew), algae, and yeasts" was added to the Approved Uses section;
- the following specific uses were deleted: building materials, concrete and materials used to make concrete, all fiber uses, and pool and spa filters; and
- the header "EPA Registration Requirements" and the paragraph "The applications for which this product is used may require approval by the Environmental '...' Protection Agency on an end-use basis..." was added (AM 500 I only).



Collateral Labeling

- as in the main label, the signal word was changed from "Danger" to "Warning" and the precautionary language was changed per the current Label Review Manual to reflect the results of the primary eye irritation study (toxicity category II);
- under the header "Primary Uses" the words "disinfectants," "sanitizers," and the phrase "..effective and active against a wide variety of bacteria, fungi, algae, and yeasts" were deleted;
- the word "broad-spectrum" was removed from the first bulleted statement under the Description section;
- the second bullet under the Description section, "Broad-spectrum activity—effective against gram positive and gram negative bacteria, fungi, algae and yeasts; antimicrobial action is exhibited on contact," was deleted;
- under the heading "Benefits" on page two of the collateral labeling, the bullets "Provides a durable, residual, antimicrobial treatment that is not destroyed by repeated cleaning" and "Contains no phenols, tin, heavy metals, lead, mercury, or formaldehyde" were removed;
- the words "disinfectants" and "sanitizers," and the use "air treatment products" were removed from the first paragraph under Approved Uses (AM 500 I only);
- the first paragraph under Approved Uses was revised to read "AM 500 is a microbiocide for use in laundry additives, carpet treatment products, upholstery and drapery treatment products, and building cleaning and treatment products" (AM 500 only);
- the phrase "incorporation into and" was removed from the third paragraph under Approved Uses (AM 500 only);
- the second paragraph under Approved Uses beginning "<u>Target Pests</u>:..." was deleted;
- the phrase "The active ingredient in AM 500 [I] is effective against fungi (including mold and mildew), algae, and yeasts" was added to the Approved Uses section;
- the following uses were deleted from the list of Approved Uses: building materials, concrete and materials used to make concrete, all fiber uses, and pool and spa filters;
- the header "EPA Registration Requirements" and the paragraph following it were removed (AM 500 I only, this paragraph is not applicable to AM 500);
- under the Environmental Hazards section, the paragraph beginning "AM 500 [I], by standard biological oxygen demand (BOD) and total oxygen demand (TOD) determination, does not appear..." was removed; and
- minor formatting changes were made to the References section.



We understand from our conversations with Dennis Edwards in March that the Primary Eye Irritation study for these products will be reviewed by the Science Branch as soon as possible. This submission of revised product labels and the primary eye irritation study will complete the requirements to process the applications for registration of BioShield AM 500 and BioShield AM 500 I.

If you have any questions, please contact me at (703) 312-8539.

Sincerely,

Kimberly Lowe

Regulatory Assistant

Jellinek, Schwartz & Connolly, Inc.

Authorized Representative of

BioShield Technologies, Inc.

Enclosures

c: Joachim Berkner



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460



BioShield Technologies, Inc. c/o Jellinek, Schwartz & Connolly, Inc. 1525 Wilson Boulevard, Suite 600 Arlington, VA 22209

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

FEB 0 5 1998

Attn: Blane Dahl

Agent for Bioshield

Subject: Application for Registration

BioShield AM 500 L

EPA File Symbol 70871-E

Your Submission Dated October 15, 1997

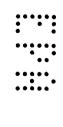
The application referred to above has been determined pursuant to 40 CFR 152.104 (53 FR 15980, May 4, 1988) not to be sufficiently complete to process; therefore, the application is considered deficient. Labeling/other information specified below must be submitted before processing of the application can be completed.

1. The Agency has reviewed your response to our requirement that you submit a primary eye irritation study (Guideline No. 81-4). You have proposed that EPA grant a conditional registration on the basis that you conduct and submit a primary eye irritation study to the Agency by June 30, 1998. Furthermore, you state that the potential overstatement of risk posed by a Category I rating for eye irritation "...will not increase any hazards to human health, but rather ensures that the proposed product is used with caution...".

The Agency does not agree with this approach to precautionary labeling since these statements provide the pesticide user with necessary information regarding the potential toxicity, irritation and sensitization hazard associated with the use of this product. Specifically, the primary eye irritation study measures the severity of irritation or corrosivity caused by the product. We do not want to mislead the user with "overlabeling". Therefore, the Agency will continue to require the submission of a primary eye irritation study prior to registration of this product.

2.	The following	comments apply	to the proposed	label for BioShield AM 500	
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a. In the ingredients statement section, add "Total Ingredients:	,
under the "Inert Ingredients:" statement.	••



- b. The proposed use for "air treatment products" is not on the product label for EPA Registration No. 34292-6 (Dow Corning 5772 MUP), the product considered substantially similar to BioShield AM 500 I. You must remove this use from the "Approved Uses" section of the label on page two.
- c. In the section for "Target Pests", you must remove the references to the specific species that have been tested. This must also be removed on the Collateral Labeling.
- d. On page three, under the "Approved Uses" section of the label, you must remove the following items: building materials; concrete and materials used to make concrete; fibers, such as polypropylene fibers, and fabrics made from those fibers; fibers, such as polypropylene fibers, and fabrics made from those fibers used for incorporation into concrete; and pool and spa filters. These uses are not on the Dow Corning 5772 MUP product label for EPA Registration No. 34292-6, or on the DowCorning 5772 end use product. You must also remove these items from page three of your Collateral labeling.
- e. On your Collateral Labeling, under the Benefits section, remove the following statements: "Provides a durable, residual, antimicrobial treatment that is not destroyed by repeated cleaning." and "Contains no phenols, tin, heavy metals, lead, mercury, or formaldehyde."
- f. Also on page three of the Collateral Labeling, under Approved Uses, remove the reference to "air treatment products" in the first paragraph.
- g. The "EPA Registration Requirements" referred to on page four of the Collateral Labeling must be moved to the product label.

If you have any questions concerning this letter, please contact Julie Fairfax at (703) 308-9086.

Sincerely yours,

Velma Noble

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510W)

Form Approved.	OMB No.	2070-0060	Approval	Expires	5-31-9



United States **Environmental Protection Agency**

Registration
Amendment
Other

OPP	ldentifier	Number

Washington, DC 20			Other			
Application for Pesticide - Section I						
Company/Product Number 70871- E		2. EPA Product		3. Pr	roposed Classi	fication
4. Company/Product (Name) BioShield AM 500 I		PM#	31		None	Restricted
5. Name and Address of Applicant (Include ZIP Code) BioShield Technologies, Inc. 4405 International Boulevard, Suite B109 Norcross, GA 30093 Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3 (c) (3) (b) (i), my product is similar or identical in composition and labeling to: EPA Reg. No. Product Name					
Grison with the teath and address	Section	า - แ			·····	
Amendment - Explain below. Resubmission in response to Agency letter dated <u>February</u>		Final pri	inted labels in res	sponse to		
Notification - Explain below. Cher - Explain below. Explanation: Use additional Page(s) if necessary. (For section I and Section II) Submission of primary eye irritation data and a revised label in response to EPA letter dated February 5, 1998						
	Section	า - III				
1. Material This Product Will Be Packaged In:						
Unit Packaging Yes* No * Certification must be submitted Unit Packaging Yes No If "Yes" Unit Packaging Yes Unit Packaging	No. per Container	Water Soluble Yes No If "Yes" Unit Package w	No. F	Per GI Pa	oe of Contained etal astic lass aper ther (Specify)	
3. Location of Net Contents Information 4. Siz	e(s) Retail Contain	er	On Lab	Label Directions el eling accompanyi	ing product	
6. Manner in Which Label is Affixed to Product	Lithograph Paper glued Stenciled		Other			
	Section					
1. Contact Point (Complete items directly below for identification of individual to be contacted if necessary to process this application.) Name Kimberly Lowe Kimberly Lowe Title Regulatory Assistant Jellinek, Schwartz & Connolly, Inc. Authorized Representative of BioShield Technologies, Inc. (703) 312-8539						
Certif I certify that the statements which I have made on this form I acknowledge that any knowingly false or misleading statem both under applicable law. 2. Signature					6. Date Appli Received (Star	
Kimberly Howe	Regulatory Assis Jellinek, Schwar Authorized Repr 5. Date	tz & Connolly, fi		ologies, Inc.	•••••	••••
berly Lowe orm 8750-1 (Rev. 8-94) Previous editions are obsolete	May 5, 1998	Wh	nite - EPA File Cop	py (original)	Yellow-	Applicant Copy

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					FQPA	
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10 Descriptor (Amend/R	esubalsion	ns only) _			old	Chamical
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	/ <u></u> / (N)	No) Service Per	
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25 Proposed Classifica						days
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135 Date on Application of the DAY	8 1041 R	MD D	3/9/8	Date Reco	DAY YR	
80 Method of Support						
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Reviewers Requested:	DATE	DATE	DATE	RESPONSE	RESPONSE DATE	
СН				-		
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PL				-		
DEB		1		-		
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TB		1	1	1	-	
EEB		1		-		
EFGB				-		
ACTION Code 3	7_		120 Respons	JUL 2	2 1099 Y YR	
75-DAY RESPONSE DUE DATE	E: //(Y) Yes	/_/(N) No			

Please read instructions on reverse before completing form.			rom A	pproved. OMB No.	2070-0000 Approval E	
United States			Registra		OPP Identifier N	umber
Environmental Protection Agency			Amendm	ent		
Washington, DC 20	460	\boxtimes	Other			
	ion for Pest					
1. Company/Product Number 70871- E			uct Manager /elma Noble	3.	Proposed Classific	ation
4. Company/Product (Name) BioShield AM 500 I		PM#	31		None	Restricted
Name and Address of Applicant (Include ZIP Code)		s Expedi	ted Review In	accordance wit	h FIFRA Section 3	l (c) (3)
BioShield Technologies, Inc.					position and labeling	
4405 International Boulevard, Suite B109		to: FPA Reg. I	No. ·			
Norcross, GA 30093						
Check if this is a new address		Product Na	me			
	Section) - II				
Amendment - Explain below.		Final	printed labels in re	esponse to		
Resubmission in response to Agency letter dated <u>February</u>	y 5, 1998	"Me	Γοο" Application.			
Notification - Explain below.		Othe	r - Explain below.			
xplanation: Use additional Page(s) if necessary. (For sect	ion I and Section II)					
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Submission of revised product label in respon	se to EPA lette	er dated F	ebruary 5, 18	190		
	Section	_ 10				
1. Material This Product Will Be Packaged In:	0001.011					
Unit Packaging		Water Solub	le Packaging	2T	ype of Container	
Child-Resistant Packaging Yes		Yes			∕letal	
Yes* No		☐ No			Plastic	
NoIf "Yes"	No. per	If "Yes"	No.	Per	Glass Paper	
* Certification must Unit Packaging wgt.	Container	Unit Package	e wgt. Conta		Other (Specify)	
be submitted						
3. Location of Net Contents Information 4. Siz	e(s) Retail Containe	er		Label Directions	6	
Label Container			On Lat			
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6. Manner in Which Label is Affixed to Product	Lithograph	_	•			
	Paper glued	L	Other			_
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	Section					
Contact Point (Complete items directly below for identification Name	Title Regulatory		ecessary to proce		on.) . (Include Area Co	do)
Kimberly Lowe	Jellinek, Schwa		ily, Inc.	(703) 312-8	•	ie)
•	Authorized Rep Technologies, I		of BioShield	,		
Certif	ication	110.			6. Date Applica	tion
I certify that the statements which I have made on this form	and all attachments			€.	Received	
I acknowledge that any knowingly false or misleading statem both under applicable law.	nent may be punisha	able by fine or	imprisonment or		(Stamp	
2. Signature	3. Title				•••••	•••••
Wimbert V.	Regulatory Assis Jellinek, Schwart		. Inc.		· · · :	••
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4. Typed Name Kimborly Love	5. Date	las				
Kimberly Lowe	9/9/	147	White EDA File O	onu (origin -1)	Vallens A	anliant C
EPA Form 8750-1 (Rev. 8-94) Previous editions are obsolete	, ,	·	White - EPA File Co	opy (original)	Jellow - Al	oplicant Copy

Jellinek, Schwartz & Connolly, Inc.

1525 Wilson Boulevard, Suite 600 Arlington, VA 22209 (703) 527-1670 • Fax: (703) 527-5477



Hand Delivered

Consultants in Environmental Science, Policy & Management

April 9, 1998

Ms. Velma Noble (Acting PM 31)
Regulatory Management Branch I
Antimicrobials Division (7510W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

Spoke with Kimberly Love
on 7/22/98. She said that
this submission is supersailed
by the one received 5/7/98.

I closed out this
submission with a 37.
(Also see highlighted
portion of FAX which
follows.) July Lext

Re: Submission of Labels in Response to EPA Letters Dated February 5,4998

AM 500 (EPA File Symbol 70871-R) AM 500 I (EPA File Symbol 70871-E)

Dear Ms. Noble:

On behalf of BioShield Technologies, Inc. (BioShield; 4405 International Boulevard, Suite B109, Norcross, Georgia, 30093), we are submitting revised labels in support of the pending registrations of BioShield AM 500 and AM 500 I (EPA File Symbols 70871-R and -E, respectively). These labels were revised as requested in two EPA letters dated February 5, 1998, one for each of these products. For both of the proposed products, enclosed please find the following materials:

- an 8570-1 form:
- copies of two EPA letters dated February 5, 1998, regarding the registrations of AM 500 and AM 500 I;
- one copy of proposed product labels submitted with the October 15, 1997, submission;
- one copy of revised, proposed product labels with revisions highlighted; and
- five copies of revised, proposed product labels.

Please note that we have removed all claims on the enclosed draft labels that require the submission of additional efficacy data. BioShield intends to submit efficacy data in the future to support certain antimicrobial claims.

Specific changes made to the proposed AM 500 and AM 500 I labeling are as follows:

Main Label

- the phrase "Total Ingredients" was added beneath the ingredients statement;
- the complete use directions were added to the Directions for Use section of the main product label (AM 500 I only, AM 500 label already had complete Directions for Use);
- under Directions for Use, the phrase "Note: This product should not be used or compounded with any bleach or oxidizing agents. Do not use in conjunction with anionic surfactants" was deleted;
- under Directions for Use, the phrase "For formulating into end-use products listed in the attached Information About Antimicrobial Agents pamphlet" was shortened to "For formulating into end-use products":
- under Approved Uses, the words "disinfectants" and "sanitizers" and the use "air treatment products" were removed from the first paragraph (AM 500 I only);
- the first paragraph under Approved was revised to read "AM 500 is a microbiocide for use in laundry additives, carpet treatment products, upholstery and drapery treatment products, and building cleaning and treatment products" (AM 500 only);
- the phrase "incorporation into and" was removed from the third paragraph under Approved Uses (AM 500 only);
- under Approved Uses, the entire paragraph beginning "<u>Target Pests</u>:..." was deleted;
- the following specific uses were deleted: building materials, concrete and materials used to make concrete, all fiber uses, and pool and spa filters; and
- the header "EPA Registration Requirements" and the paragraph "The applications for which this product is used may require approval by the Environmental Protection Agency on an end-use basis..." was added (AM 500 I only).

Collateral Labeling

- under the header "Primary Uses" the words "disinfectants," "sanitizers," and the phrase "..effective and active against a wide variety of bacteria, fungi, algae, and yeasts" were deleted;
- the word "broad-spectrum" was removed from the first bulleted statement under the Description section;
- the second bullet under the Description section, "Broad-spectrum activity—effective against gram positive and gram negative bacteria, fungi, algae and yeasts; antimicrobial action is exhibited on contact," was deleted;
- under the heading "Benefits" on page two of the collateral labeling, the bullets "Provides a durable, residual, antimicrobial treatment that is not destroyed by repeated cleaning" and "Contains no phenols, tin, heavy metals, lead, mercury, or formaldehyde" were removed;



- the words "disinfectants" and "sanitizers," and the use "air treatment products" were removed from the first paragraph under Approved Uses (AM 500 I only);
- the first paragraph under Approved Uses was revised to read "AM 500 is a
 microbiocide for use in laundry additives, carpet treatment products, upholstery and
 drapery treatment products, and building cleaning and treatment products" (AM
 500 only);
- the phrase "incorporation into and" was removed from the third paragraph under Approved Uses (AM 500 only);
- the second paragraph under Approved Uses beginning "<u>Target Pests</u>:..." was deleted;
- the following uses were deleted from the list of Approved Uses: building materials, concrete and materials used to make concrete, all fiber uses, and pool and spa filters;
- the header "EPA Registration Requirements" and the paragraph following it were removed (AM 500 I only, this paragraph is not applicable to AM 500); and
- under the Environmental Hazards section, the paragraph beginning "AM 500 [1], by standard biological oxygen demand (BOD) and total oxygen demand (TOD) determination, does not appear..." was removed.

As requested in your February 5, 1998, letters, BioShield is in the process of conducting a primary eye irritation study on AM 500 and AM 500 I. As soon as this study is complete, we will submit it to EPA for review. We understand from our recent conversations with Julie Fairfax that submission of the enclosed revised product labels and this primary eye irritation study will complete the requirements to process the applications for AM 500 and AM 500 I and that there are no other outstanding issues in the way of regulatory approval.

If you have any questions, please contact me at (703) 312-8539.

Sincerely,

Kimberly Lowe
Regulatory Assistant

Jellinek, Schwartz & Connolly, Inc.

Authorized Representative of BioShield Technologies, Inc.

Enclosures

c: Joachim Berkner

Jellinek, Schwartz & Connolly, Inc.

1525 Wilson Boulevard, Suite 600 Arlington, VA 22209 (703) 527-1650 • Fax: (703) 527-5477

AN COMPANY



Hand Delivered

May 5, 1998

Ms. Velma Noble (Acting PM 31)
Regulatory Management Branch I
Antimicrobials Division (7510W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

Re: Submission of Labels and a Primary Eye Irritation Study in Response to EPA Letters Dated February 5, 1998
BioShield AM 500 and AM 500 I (EPA File Symbols 70871-R and -E)

Dear Ms. Noble:

On behalf of BioShield Technologies, Inc. (BioShield, 4405 International Boulevard, Suite B109, Norcross, Georgia, 30093), we are submitting revised labels and a primary eye irritation study (EPA Guideline Number 81-4) in support of the pending registrations of BioShield AM 500 and AM 500 I (EPA File Symbols 70871-R and -E, respectively). This submission is in response to two EPA letters dated February 5, 1998, one for each of these products. For both of the proposed products, enclosed are the following materials:

- an 8570-1 form;
- copies of two EPA letters dated February 5, 1998, regarding the registrations of BioShield AM 500 and AM 500 I;
- one copy of proposed product labels submitted on October 15, 1997;
- one copy of revised, proposed product labels with revisions highlighted;
- five copies of revised, proposed product labels; and
- three copies of a study titled Primary Eye Irritation Study in Rabbits (EPA Guideline No. 81-4).

Please note that the revised, draft labeling submitted in this package supersedes the labeling submitted in the package dated April 9, 1998. Also, we have removed all claims on the enclosed draft labels that require the submission of additional efficacy data. BioShield intends to submit efficacy data in the future to support certain antimicrobial claims.

Specific changes made to the proposed BioShield AM 500 and AM 500 I labeling are as follows:

Main Label

- the phrase "Total Ingredients" was added beneath the ingredients statement;
- the signal word was changed from "Danger" to "Warning" and the precautionary language was changed per the current Label Review Manual to reflect the results of the primary eye irritation study (toxicity category II);
- the complete use directions were added to the Directions for Use section (AM 500 I only, AM 500 label already had complete Directions for Use);
- under Directions for Use, the phrase "Note: This product should not be used or compounded with any bleach or oxidizing agents. Do not use in conjunction with anionic surfactants" was deleted;
- under Directions for Use, the phrase "For formulating into end-use products listed in the attached Information About Antimicrobial Agents pamphlet" was shortened to "For formulating into end-use products";
- under Approved Uses, the words "disinfectants" and "sanitizers" and the use "air treatment products" were removed from the first paragraph (AM 500 I only);
- the first paragraph under Approved Uses was revised to read "AM 500 is a
 microbiocide for use in laundry additives, carpet treatment products, upholstery and
 drapery treatment products, and building cleaning and treatment products" (AM
 500 only);
- the phrase "incorporation into and" was removed from the third paragraph under Approved Uses (AM 500 only);
- under Approved Uses, the entire paragraph beginning "Target Pests:..." was deleted;
- the phrase "The active ingredient in AM 500 [I] is effective against fungi (including mold and mildew), algae, and yeasts" was added to the Approved Uses section;
- the following specific uses were deleted: building materials, concrete and materials used to make concrete, all fiber uses, and pool and spa filters; and
- the header "EPA Registration Requirements" and the paragraph "The applications for which this product is used may require approval by the Environmental Protection Agency on an end-use basis..." was added (AM 500 I only).

Collateral Labeling

- as in the main label, the signal word was changed from "Danger" to "Warning" and the precautionary language was changed per the current Label Review Manual to reflect the results of the primary eye irritation study (toxicity category II);
- under the header "Primary Uses" the words "disinfectants," "sanitizers," and the phrase "..effective and active against a wide variety of bacteria, fungi, algae, and yeasts" were deleted;
- the word "broad-spectrum" was removed from the first bulleted statement under the Description section;
- the second bullet under the Description section, "Broad-spectrum activity—effective against gram positive and gram negative bacteria, fungi, algae and yeasts; antimicrobial action is exhibited on contact." was deleted:
- under the heading "Benefits" on page two of the collateral labeling, the bullets "Provides a durable, residual, antimicrobial treatment that is not destroyed by repeated cleaning" and "Contains no phenols, tin, heavy metals, lead, mercury, or formaldehyde" were removed;
- the words "disinfectants" and "sanitizers," and the use "air treatment products" were removed from the first paragraph under Approved Uses (AM 500 I only);
- the first paragraph under Approved Uses was revised to read "AM 500 is a
 microbiocide for use in laundry additives, carpet treatment products, upholstery and
 drapery treatment products, and building cleaning and treatment products" (AM
 500 only);
- the phrase "incorporation into and" was removed from the third paragraph under Approved Uses (AM 500 only);
- the second paragraph under Approved Uses beginning "Target Pests:..." was deleted:
- the phrase "The active ingredient in AM 500 [I] is effective against fungi (including mold and mildew), algae, and yeasts" was added to the Approved Uses section;
- the following uses were deleted from the list of Approved Uses: building materials, concrete and materials used to make concrete, all fiber uses, and pool and spa filters;
- the header "EPA Registration Requirements" and the paragraph following it were removed (AM 500 I only, this paragraph is not applicable to AM 500);
- under the Environmental Hazards section, the paragraph beginning "AM 500 [I], by standard biological oxygen demand (BOD) and total oxygen demand (TOD) determination, does not appear..." was removed; and
- minor formatting changes were made to the References section.

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We understand from our conversations with Dennis Edwards in March that the Primary Eye Irritation study for these products will be reviewed by the Science Branch as soon as possible. This submission of revised product labels and the primary eye irritation study will complete the requirements to process the applications for registration of BioShield AM 500 and BioShield AM 500 I.

If you have any questions, please contact me at (703) 312-8539.

Sincerely,

Kimberly Lowe
Regulatory Assistant

Jellinek, Schwartz & Connolly, Inc.

Authorized Representative of BioShield Technologies, Inc.

Enclosures

c: Joachim Berkner

BioShield Technologies, Inc.

4405 International Boulevard, Suite B109 Norcross, GA 30093

BioShield AM 500 I

ANTIMICROBIAL AGENT & PROTECTANT

A Silicone Quaternary Ammonium Salt (For Manufacturing Use Only)

92.0% 100.0% 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride...... Active Ingredient: Inert Ingredients: INGREDIENTS:

KEEP OUT OF REACH OF CHILDREN DANGER

Lot No. _____ EPA Reg. No. xxxx-xx

EPA EST. xxxxx-GA-xx

NET CONTENTS: 8 oz., 1 gal., 5 gal., or 55 gal.

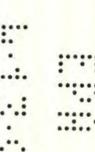
STATEMENT OF PRACTICAL TREATMENT

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.

person. Drink promptly a large quantity of milk, eggwhites, gelatin solution, or, if these are not available, drink large quantities of IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious water. Avoid alcohol.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.



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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

and protective eyewear (goggles and face shield). Wash thoroughly with soap and water after handling and before eating, drinking, inhaled. Harmful if inhaled. Avoid contact with skin, eyes, or clothing. Avoid breathing vapor. Wear protective clothing and gloves, Corrosive. Causes irreversible eye damage. May be fatal if swallowed. Causes skin irritation. Harmful if absorbed through skin or using tobacco, or using the toilet. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in

De-activation of AM 500 I can be achieved by the addition of anionic surfactant in quantity equivalent to that of AM 500 I.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

AM 500 I can be incorporated directly into formulations used to make the end products listed under "approved uses."

inorganic substrates by brushing, dipping, padding, soaking, spraying, fogging or by using foam finishing techniques to give a final AM 500 I can also be diluted with water or other solvents (for example, alcohol, and ketones) and then applied to organic or treatment of 0.1 to 1.0 percent by weight active ingredient. After applying the antimicrobial agent, the substrate can then be dried at temperatures from ambient to a maximum of 160° C (320° Optimum application and drying conditions, such as time and temperature, should be determined for each application before use. F) to effect complete condensation of silanol groups and to remove water, solvents and/or traces of methanol from hydrolysis.

For formulating use into end-use products.

APPROVED USES

AM 500 l is approved for use in formulating microbiocides for use in laundry additives, carpet treatment products, upholstery and drapery treatment products, and building cleaning and treatment products.

AM 500 I can be used for incorporation into and treatment of the following items or substrates to impart durable antimicrobial protection:

- Air filters for furnaces, air-conditioners, air purification devices, automobiles, recirculating air handling systems;
- Air filters/materials;
- Aquarium filter material;
- Bed sheets, blankets, and bedspreads;
- Buffer pads (abrasive and polishing);
- Carpets and draperies;
- Fiberfill for upholstery, sleeping bags, apparel, etc., where the fiber is cotton, natural down, nylon, polyester, rayon, or wool;
 - Fiberglass ductboard;
- Fire hose fabric;
 - Humidifier belts;
- Mattress pads and ticking;
- Men's underwear and outerwear;
- Non-woven disposable diapers;
- Non-woven polyester;
 - Outerwear apparel;
- Disposable polyurethane foam cushions for Lapidus Airfloat Systems;
- Polyurethane foam for household, industrial, and institutional sponges and mops;
 - Polyurethane and polyethylene foam, when covered;
- Polyurethane foam for packaging and cushioning in non-food contact applications;
 - Polyurethane foam used as a growth medium for non-food crops and plants;
- Pre-moistened towelettes and tissue wipes (these do not impart pesticidal properties);
- Roofing materials defined as shingles, roofing granules, wood shakes, felt, stone and synthetic overcoats;
 - Sand bags, tents, tarpaulins, sails, and ropes;
- Athletic and casual shoes;
 - יייי ייייי אוויייייט מואמוייי
 - Shoe insoles;
- Shower curtains;
- Socks comprised of nylon, nylon/orlon, cotton/nylon, linen/Lycra, acrylic/polypropylene/nylon/Lycra, wool/silk/nylon/Lycra and wool/acrylic/nylon/Lycra;
 - Throw rugs;
- Toweling made of 100 percent cotton, 100 percent polyester, and blends of the two fibers;
 - Toilet tank and seat covers;
 - Umbrellas;
- Upholstery made of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polyolefins, polypropylene, rayon, spandex, vinyl, and wool;
- Vacuum cleaner bags and filters;
- Vinyl paper-wallpaper for non-food contact surfaces;

ing furniture, cars, walls, windows, floors, appliances, or multiple purposes such as dusting or w dishes, counter tops, etc.; the wiping cloths do not impart pesticide properties; Disposable wiping cloths that can be us.

Women's hosiery; and

Women's intimate apparel.

EPA REGISTRATION REQUIREMENTS

The applications for which this product is used may require approval by the Environmental Protection Agency on an end-use basis in regard to claims made thereof. Formulators are responsible for satisfying registration requirements for their products.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

inaccessible to children and away from food or feed. AM 500 I has a minimum shelf life of 12 months from the date of shipment Pesticide Storage: Store in original, tightly closed containers below 30°C (86°F) and above 0°C (32°F) in a secure area from BioShield

violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

FOR MORE INFORMATION CONCERNING THIS PRODUCT, PLEASE CONSULT THE MATERIAL SAFETY DATA SHEET (MSDS). THE MSDS CAN BE OBTAINED BY WRITING BIOSHIELD TECHNOLOGIES, INC. AT 4405 INTERNATIONAL BOULEVARD, SUITE B109, NORCROSS, GEORGIA, 30093

COLLATERAL LABELING

BioShield Technologies, Inc.

4405 International Boulevard, Suite B109 Norcross, GA 30093

Information About Antimicrobial Agents

AM 500 I — FOR MANUFACTURING USE ONLY					
U.S. Environmental Protection Agency Registration Number					
	Silicone quaternary ammonium salt				
Physical Form	Low-viscosity liquid				
	Surface bondability				
Primary Uses	As an active ingredient for formulating				
	microbiocides for use in laundry additives,				
	carpet treatment products, upholstery and				
	drapery treatment products, and building				
	cleaning and treatment products to give a				
	surface-durable antimicrobial treatment				

TYPICAL PROPERTIES

These values are not intended for use in preparing specifications.

These values are not interluce for use in preparing specime	ations
Structure	CH₃ .[(CH₃O)₃Si(CH₂)₃N–C₁8H₃7] [†] Cl ⁻
	CH ₃
Concentration	5.0%
Appearance	Colorless liquid
Solubility	Miscible in all proportions with
·	water, ethanol, and methanol
Thermal Stability °C (°F)	Stable to 30°C (86°F)
Specification Writers: Please contact BioShield for informatio	n regarding specifications

DESCRIPTION

AM 500 I is BioShield's designation for 3-(trimethoxysilyI) propyloctadecyldimethyl ammonium chloride containing 5 percent active ingredient by weight. Alkoxysilanes of this nature have been shown to form durable bonded coatings to a number of materials (see "References" section).

AM 500 I offers users the following features:

- Good durability—BIOSHIELD AM 500 I Antimicrobial Agent imparts durable biostatic activity to the surface of a wide variety of substrates; it is leach-resistant and nonmigrating and is not consumed by microorganisms.
- Increased efficiency—through proper application, durable bacteriostatic, fungistatic and algistatic surfaces can be attained with a minimum amount of AM 500 I.

BENEFITS

The following benefits are derived when a formulation containing the active ingredient is applied to a surface:

- Provides hygienic freshness and combats deterioration caused by bacteria, fungi, algae, and yeasts.
- Inhibits growth of bacteria and mildew on the treated article.
- Prolongs the life of a article by inhibiting the growth of bacteria and mildew.
- Resists development of bacterial and fungal odors.
- Retains freshness by resisting the growth of odor-causing bacteria and mildew (fungus).
- Provides a chemical treatment that enables fabrics to resist odors.
- Provides a unique chemical treatment that resists mildew and bacteria growth and imparts odor resistance.
- Product performance with little degradation up to 375°F.

Materials treated with formulations containing the antimicrobial agent AM 500 I are preserved by the bacteriostatic, fungistatic and algistatic action imparted by the active ingredient. AM 500 I inhibits the growth of microorganisms that are responsible for causing odor, discoloration and deterioration. It also provides residual inhibition of microorganisms to aid in the control of these deleterious effects. AM 500 I forms a coating on a wide variety of substrates and antimicrobial action is exhibited on contact.

APPROVED USES

AM 500 I is approved for use in formulating microbiocides for use in laundry additives, carpet treatment products, upholstery and drapery treatment products, and building cleaning and treatment products.

AM 500 I can be used for incorporation into and treatment of the following items or substrates to impart durable antimicrobial protection:

- Air filters for furnaces, air-conditioners, air purification devices, automobiles, recirculating air handling systems;
- Air filters/materials;
- Aguarium filter material;
- · Bed sheets, blankets, and bedspreads;
- Buffer pads (abrasive and polishing);
- · Carpets and draperies;
- Fiberfill for upholstery, sleeping bags, apparel, etc., where the fiber is cotton, natural down, nylon, polyester, rayon, or wool;
- · Fiberglass ductboard;
- Fire hose fabric;
- Humidifier belts;
- Mattress pads and ticking;
- Men's underwear and outerwear;
- Non-woven disposable diapers;
- Non-woven polyester;
- Outerwear apparel;
- Disposable polyurethane foam cushions for Lapidus Airfloat Systems;
- Polyurethane foam for household, industrial, and institutional sponges and mops;
- Polyurethane and polyethylene foam, when covered;
- Polyurethane foam for packaging and cushioning in non-food contact applications;
- Polyurethane foam used as a growth medium for non-food crops and plants;
- Pre-moistened towelettes and tissue wipes (these do not impart pesticidal properties);
- Roofing materials defined as shingles, roofing granules, wood shakes, felt, stone and synthetic overcoats;
- Sand bags, tents, tarpaulins, sails, and ropes;
- Athletic and casual shoes;
- · Shoe insoles:
- Shower curtains;
- Socks comprised of nylon, nylon/orlon, cotton/nylon, linen/Lycra, acrylic/polypropylene/nylon/Lycra, wool/silk/nylon/Lycra and wool/acrylic/nylon/Lycra;
- Throw rugs:
- Toweling made of 100 percent cotton, 100 percent polyester, and blends of the two fibers;
- Toilet tank and seat covers:
- Umbrellas:
- Upholstery made of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polyolefins, polypropylene, rayon, spandex, vinyl, and wool;
- · Vacuum cleaner bags and filters;
- · Vinyl paper-wallpaper for non-food contact surfaces;
- Disposable wiping cloths that can be used for multiple purposes such as dusting or washing furniture, cars, walls, windows, floors, appliances, dishes, counter tops, etc.; the wiping cloths do not impart pesticide properties;
- Women's hosiery; and
- Women's intimate apparel.

DIRECTIONS FOR USE

AM 500 I can be incorporated directly into formulations used to make the end products listed in this bulletin.

AM 500 I can also be diluted with water or other solvents (for example, alcohol, and ketones) and then applied to organic or inorganic substrates by brushing, dipping, padding, soaking, spraying, fogging or by using foam finishing techniques to give a final treatment of 0.1 to 1.0 percent by weight active ingredient.

After applying the antimicrobial agent, the substrate can then be dried at temperatures from ambient to a maximum of 160° C (320° F) to effect complete condensation of silanol groups and to remove water, solvents and/or traces of methanol from hydrolysis. Optimum application and drying conditions, such as time and temperature, should be determined for each application before use.

PRECAUTIONARY STATEMENTS

Corrosive. Causes irreversible eye damage. May be fatal if swallowed. Causes skin irritation. Harmful if absorbed through skin or inhaled. Harmful if inhaled. Avoid contact with skin, eyes, or clothing. Avoid breathing vapor. Wear protective clothing and gloves, and protective eyewear (goggles and face shield). Wash thoroughly with soap and water after handling and before eating, drinking, using tobacco, or using the toilet. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark; this product might be toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

Inactivation of solutions containing AM 500 I may be accomplished by one of the following methods:

- addition of an anionic surfactant or detergent in quantity equivalent to that of AM 500 I in solution; or
- addition of Triton X-100 nonionic detergent at a final concentration of 10,000 ppm (1.0 percent volume/volume) or greater to bath solutions up to 1.0 percent volume/volume of AM 500 l.

Every effort should be made to contain accidental spills of AM 500 I to the immediate area. This may be accomplished by the use of sandbags to confine the spill to facilitate cleanup and disposal. Contaminated sand may then be disposed of by burial in an approved landfill. Many spills may be cleaned up with rags by wiping and/or mopping and allowing the liquid to absorb into the fabric. The rags may then be disposed of by incineration.

Floor drains in areas of material use should be protected with sandbags to contain accidental spills.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in original, unopened containers below 3°C (86°F) and above 0°C (32°F). AM 500 I has a minimum shelf life of 12 months from the date of shipment from BioShield.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Before handling, read product label in its entirety

IMPORTANT: WARRANTY AND DISCLAIMER INFORMATION

BioShield Technologies, Inc., warrants that the product conforms to its chemical description and is reasonably fit for the purposes stated in this bulletin when used in accordance with directions under normal conditions of use; but this warranty of fitness for a particular purpose does not extend to the use of this product contrary to bulletin instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to seller, and buyer assumes the risk of any such use.

BIOSHIELD SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING THE WARRANTY OF MERCHANTABILITY.

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BioShield Technologies, Inc. 4405 International Boulevard, Suite B109 Norcross, GA 30093

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BioShield Technologies, Inc. c/o Jellinek, Schwartz & Connolly, Inc. 1525 Wilson Boulevard, Suite 600 Arlington, VA 22209

FEB 0 5 1998

Attn: Blane Dahl

Agent for Bioshield

Subject: Application for Registration

BioShield AM 500 I EPA File Symbol 70871-E

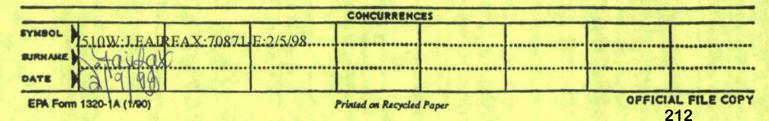
Your Submission Dated October 15, 1997

The application referred to above has been determined pursuant to 40 CFR 152.104 (53 FR 15980, May 4, 1988) not to be sufficiently complete to process; therefore, the application is considered deficient. Labeling/other information specified below must be submitted before processing of the application can be completed.

1. The Agency has reviewed your response to our requirement that you submit a primary eye irritation study (Guideline No. 81-4). You have proposed that EPA grant a conditional registration on the basis that you conduct and submit a primary eye irritation study to the Agency by June 30, 1998. Furthermore, you state that the potential overstatement of risk posed by a Category I rating for eye irritation "...will not increase any hazards to human health, but rather ensures that the proposed product is used with caution...".

The Agency does not agree with this approach to precautionary labeling since these statements provide the pesticide user with necessary information regarding the potential toxicity, irritation and sensitization hazard associated with the use of this product. Specifically, the primary eye irritation study measures the severity of irritation or corrosivity caused by the product. We do not want to mislead the user with "overlabeling". Therefore, the Agency will continue to require the submission of a primary eye irritation study prior to registration of this product.

- 2. The following comments apply to the proposed label for BioShield AM 500 I:
- a. In the ingredients statement section, add "Total Ingredients:" under the "Inert Ingredients:" statement.



Jellinek, Schwartz & Connolly, Inc. An IT Company



1525 Wilson Blvd., Suite 600 Arlington, VA 22209-241) (703) 527-1670 • Fax (703) 527-5477

Consultants in Environmental Science, Policy & Management

TO:

(Individual)

Tracy Lantz

(Company)

U.S. Environmental Protection Agency

(Phone)

(703) 308-6415

(Fax#)

(703) 308-6467

FROM:

Kimberly Lowe

DATE:

July 22, 1998

TIME:

2:01 PM

OF PAGES (including cover sheet):

Kimberly

5

IF COPY IS ILLEGIBLE OR INCOMPLETE, PLEASE CALL (703) 312-8539

COMMENTS:

Dear Ms. Lantz,

As we discussed this morning, attached is a copy of the cover letter from a May 5, 1998, package submitted in support of the registration applications for BioShield AM 500 and AM 500 I (EPA Files Symbols 70871-R and -E, respectively).

Please call me at (703) 312-8539 if you have any questions.

Best regards,

The information contained in this facsimile message is intended only for the use of the individuals to whom it is addressed and may contain information that is privileged and confidential. If the reader of this message is not the intended recipient, you are hereby notified that any use, dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify us immediately at (703) 527-1670. Thank you.

- b. The proposed use for "air treatment products" is not on the product label for EPA Registration No. 34292-6 (Dow Corning 5772 MUP), the product considered substantially similar to BioShield AM 500 I. You must remove this use from the "Approved Uses" section of the label on page two.
- c. In the section for "Target Pests", you must remove the references to the specific species that have been tested. This must also be removed on the Collateral Labeling.
- d. On page three, under the "Approved Uses" section of the label, you must remove the following items: building materials; concrete and materials used to make concrete; fibers, such as polypropylene fibers, and fabrics made from those fibers; fibers, such as polypropylene fibers, and fabrics made from those fibers used for incorporation into concrete; and pool and spa filters. These uses are not on the Dow Corning 5772 MUP product label for EPA Registration No. 34292-6, or on the DowCorning 5772 end use product. You must also remove these items from page three of your Collateral labeling.
- e. On your Collateral Labeling, under the Benefits section, remove the following statements: "Provides a durable, residual, antimicrobial treatment that is not destroyed by repeated cleaning." and "Contains no phenols, tin, heavy metals, lead, mercury, or formaldehyde."
- f. Also on page three of the Collateral Labeling, under Approved Uses, remove the reference to "air treatment products" in the first paragraph.
- g. The "EPA Registration Requirements" referred to on page four of the Collateral Labeling must be moved to the product label.

If you have any questions concerning this letter, please contact Julie Fairfax at (703) 308-9086.

Sincerely yours,

Velma Noble

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510W)

Enclosure

4405 International Boulevard, Suite B109 Norcross, GA 30093

BioShield AM 500 I

ANTI-MICROBIAL AGENT & PROTECTANT

A Silicone Quaternary Ammonium Salt (For Manufacturing Use Only)

2.0%	82.0%	100.0%
3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride		
Active Ingredient:	Inert Ingredients:	

KEEP OUT OF REACH OF CHILDREN DANGER

EPA Reg. No. xxxx-xx Lot No.

EPA EST. xxxxx-GA-xx

NET CONTENTS: 8 oz., 1 gal., 5 gal., or 55 gal.

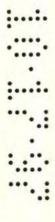
STATEMENT OF PRACTICAL TREATMENT

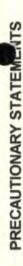
IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.

person. Drink promptly a large quantity of milk, eggwhites, gelatin solution, or, if these are not available, drink large quantities of IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious water. Avoid alcohol,

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.





HAZARDS TO HUMANS AND DOMESTIC ANIMALS

and protective eyewear (goggles and face shield). Wash thoroughly with soap and water after handling and before eating, drinking, inhaled. Harmful if inhaled. Avoid contact with skin, eyes, or clothing. Avoid breathing vapor. Wear protective clothing and gloves, Corrosive. Causes irreversible eye damage. May be fatal if swallowed. Causes skin irritation. Harmful if absorbed through skin or using tobacco, or using the toilet. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in

De-activation of AM 500 I can be achieved by the addition of anionic surfactant in quantity equivalent to that of AM 500 I.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

SEE COLLATERAL LABEL FOR COMPLETE USE DIRECTIONS

NOTE: This product should not be used or compounded with any bleach or oxidizing agents. Do not use in conjunction with anionic surfactants

For formulating use into end-use products listed in the attached "Information About Antimicrobial Agents" pamphlet.

APPROVED USES. ..

AM 500 I is approved for use in formulating disinfectants, sanitizers and microbiocides for use in laundry additives, carpet treatment products, upholstery and drapery treatment products, building cleaning and treatment products, and air treatment products. Target Pests: The active ingredient in AM 500 Lis effective against gram positive and gram negative bacteria, fungi (including mold and mildew), algae, and yeasts. The following species have been tested: Salmonella choleraesius, Staphylococcus aureas, Pseudomonas aeruginosa, Straptococcus faecalis, Eschericia coli, Asperillus niger, and Trichophyton interdigitale.

AM 500 I can be used for incorporation into and treatment of the following items or substrates to impart durable, broad-spectrum, antimicrobial protection:

- Air filters for furnaces, air-conditioners, air purification devices, automobiles, recirculating air handling systems;
 - Air filters/materials;
- Aquarium filter material;
- Bed sheets, blankets, and bedspreads;
- Buffer pads (abrasive and polishing);
 - Building materials;
- Carpets and draperies;
- Concrete and materials used to make concrete;
- Fibers, such as polypropylene fibers, and fabrics made from those fibers;
- Fibers, such as polypropylene fibers, and fabrics made from those fibers used for incorporation into concrete;
- Fiberfill for upholstery, sleeping bags, apparel, etc., where the fiber is cotton, natural down, nylon, polyester, rayon, or wool;
 - Fiberglass ductboard
 - Fire hose fabric;
- Humidifier belts;
- Mattress pads and ticking;
- Men's underwear and outerwear;
- Non-woven disposable diapers;
 - Non-woven polyester;
 - Outerwear apparel;
- Polyurethane foam for household, industrial, and institutional sponges and mops; Disposable polyurethane foam cushions for Lapidus Airfloat Systems;
- Polyurethane and polyethylene foam, when covered;
- Polyurethane foam for packaging and cushioning in non-food contact applications;
- Polyurethane foam used as a growth medium for non-food crops and plants;
- Pool and spa filters;
- Pre-moistened towelettes and tissue wipes (these do not impart pesticidal properties);
- Roofing materials defined as shingles, roofing granules, wood shakes, felt, stone and synthetic overcoats;
 - Sand bags, tents, tarpaulins, sails, and ropes;
- Athletic and casual shoes;
- Shower curtains; Shoe insales; ..
- wool/acrylic/nylon/Lycra; provides residual self-sanitizing activity against athlete's foot fungus (Trichophyton mentagrophytes) on the sock, Socks comprised of nylon, nylon/orlon, cotton/nylon, linen/Lycra, acrylic/polypropylene/nylon/Lycra, wool/silk/nylon/Lycra and durable for up to 10 repeated washings; prevents 99.9 percent of the growth of athlete's foot fungus on the sock;
 - Throw rugs;
- Toweling made of 100 percent cotton, 100 percent polyester, and blends of the two fibers;
 - Toilet tank and seat covers;

- Upholstery made of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethyene, polyolefins, polypropylene, rayon, spandex, vinyl,
- Vacuum cleaner bags and filters;
- Vinyl paper-wallpaper for non-food contact surfaces;
- Disposable wiping cloths that can be used for multiple purposes such as dusting or washing furniture, cars, walls, windows, floors, appliances, dishes, counter tops, etc.; the wiping cloths do not impart pesticide properties;
 - Women's hosiery; and
- Women's intimate apparel.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

inaccessible to children and away from food or feed. AM 500 I has a minimum shelf life of 12 months from the date of shipment Pesticide Storage: Store in original, tightly closed containers below 30°C (86°F) and above 0°C (32°F) in a secure area from BioShield.

violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

FOR MORE INFORMATION CONCERNING THIS PRODUCT, PLEASE CONSULT THE MATERIAL SAFETY DATA SHEET (MSDS). THE MSDS CAN BE OBTAINED BY WRITING BIOSHIELD TECHNOLOGIES, INC. AT 4405 INTERNATIONAL BOULEVARD, SUITE \$109, NORCROSS, GEORGIA, 30093.



COLLATERAL LABELING

BioShield Technologies, Inc.

4405 International Boulevard, Suite B109 Norcross, GA 30093

Information About Antimicrobial Agents

AM 500 I — FOR MAN	IUFACTURING USE ONLY
U.S. Environmental Protection Agency Registration Number	on r
	Silicone quaternary ammonium salt
Physical Form	Low-viscosity liquid
	Surface bondability
•	As an active ingredient for formulating disinfectants,
	sanitizers and microbiocides for use in laundry additives, carpet treatment products, upholstery and drapery
	treatment products, and building cleaning and
	treatment products to give a surface-durable
	antimicrobial treatment effective and active against
	a wide variety of bacteria, fungi, algae and yeasts

TYPICAL PROPERTIES

DESCRIPTION

AM 500 I is BioShield's designation for 3-(trimethoxysilyI) propyloctadecyldimethyl ammonium chloride containing 5 percent active ingredient by weight. Alkoxysilanes of this nature have been shown to form durable bonded coatings to a number of materials (see "References" section).

AM 500 I offers users the following features:

- Good durability—BIOSHIELD AM 500 I Antimicrobial Agent imparts durable, broad-spectrum, biostatic activity to the surface of a wide variety of substrates; it is leach-resistant and nonmigrating and is not consumed by microorganisms.
- Broad-spectrum activity—effective against gram positive and gram negative bacteria, fungi, algae and yeasts; antimicrobial action is exhibited on contact.
- Increased efficiency—through proper application, durable bacteriostatic, fungistatic and algistatic surfaces can be attained with a minimum amount of AM 500 I.

BENEFITS

The following benefits are derived when a formulation containing the active ingredient is applied to a surface:

- Provides hygienic freshness and combats deterioration caused by bacteria, fungi, algae, and yeasts.
- Inhibits growth of bacteria and mildew on the treated article.
- Prolongs the life of a article by inhibiting the growth of bacteria and mildew.

Provides a durable, residual, antimicrobial treatment that is not destroyed by repeated cleaning.

- Resists development of bacterial and fungal odors.
- Retains freshness by resisting the growth of odor-causing bacteria and mildew (fungus).
- Provides a chemical treatment that enables fabrics to resist odors.
- Provides a unique chemical treatment that resists mildew and bacteria growth and imparts odor resistance.



Contains no phenols, tin, heavy metals, lead, mercury, or formaldehyde.

Product performance with little degradation up to 375°F.

Materials treated with formulations containing the antimicrobial agent AM 500 I are preserved by the bacteriostatic, fungistatic and algistatic action imparted by the active ingredient. AM 500 I inhibits the growth of microorganisms that are responsible for causing odor, discoloration and deterioration. It also provides residual inhibition of microorganisms to aid in the control of these deleterious effects. W 500 I forms a coating on a wide variety of substrates and antimicrobial action is exhibited of contact.

APPROVED USES

AM 500 I is approved for use in formulating disinfectants, sanitizers and microbiocides for use in laundry additives, carpet treatment products, upholstery and drapery treatment products, building cleaning and treatment products, and air treatment products.

<u>Target Pests:</u> The active ingredient in AM 500 I is effective against gram positive and gram negative bacteria, fungi (including mold and mildew), algae, and yeasts. The following species have been tested: Salmonella choleraesius, Staphylococcus aureas, Pseudomonas aeruginosa, Streptococcus faecalis, Eschericia coli, Asperillus niger, and Trichophyton interdigitale.

AM 500 I can be used for incorporation into and treatment of the following items or substrates to impart durable, broad-spectrum, antimicrobial protection:

- Air filters for furnaces, air-conditioners, air purification devices, automobiles, recirculating air handling systems;
- Air filters/materials:
- Aguarium filter material;
- Bed sheets, blankets, and bedspreads;
- Buffer pads (abrasive and polishing);
- Building materials;
- Carpets and draperies;
 - Concrete and materials used to make concrete;
 - Fibers, such as polypropylene fibers, and fabrics made from those fibers;
- Fibers, such as polypropylene fibers, and fabrics made from those fibers used for incorporation into concrete;
- Fiberfill for upholstery, sleeping bags, apparel, etc., where the fiber is cotton, natural down, nylon, polyester, rayon, or wool;
- Fiberglass ductboard;
- Fire hose fabric;
- Humidifier belts:
- · Mattress pads and ticking;
- · Men's underwear and outerwear;
- Non-woven disposable diapers;
- Non-woven polyester;
- Outerwear apparel;
- Disposable polyurethane foam cushions for Lapidus Airfloat Systems;
- Polyurethane foam for household, industrial, and institutional sponges and mops;
- Polyurethane and polyethylene foam, when covered:
- Polyurethane foam for packaging and cushioning in non-food contact applications;
- Polyurethane foam used as a growth medium for non-food crops and plants;
- Pool and spa filters;
- Pre-moistened towelettes and tissue wipes (these do not impart pesticidal properties);
- Roofing materials defined as shingles, roofing granules, wood shakes, felt, stone and synthetic overcoats;
- Sand bags, tents, tarpaulins, sails, and ropes;
- Athletic and casual shoes:
- · Shoe insoles:
- Shower curtains;
- Socks comprised of nylon, nylon/orlon, cotton/nylon, linen/Lycra, acrylic/polypropylene/nylon/Lycra wool/silk/nylon/Lycra and wool/acrylic/nylon/Lycra; provides residual self-sanitizing activity against athlete's foot fungus (*Trichophyton mentagrophytes*) on the sock, durable for up to 10 repeated washings; prevents 99.9 percent of the growth of athlete's foot fungus on the sock;
- Throw rugs;
- Toweling made of 100 percent cotton, 100 percent polyester, and blends of the two fibers;
- Toilet tank and seat covers;
- Umbrellas;



- Upholstery made of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polyolefins, polypropylene, rayon, spandex, vinyl, and wool;
- · Vacuum cleaner bags and filters;
- Vinyl paper-wallpaper for non-food contact surfaces;
- Disposable wiping cloths that can be used for multiple purposes such as dusting or washing furniture, cars, walls, windows, floors, appliances, dishes, counter tops, etc.; the wiping cloths do not impart pesticide properties;
- Women's hosiery; and
- Women's intimate apparel.

DIRECTIONS FOR USE

AM 500 I can be incorporated directly into formulations used to make the end products listed in this bulletin.

AM 500 I can also be diluted with water or other solvents (for example, alcohol, and ketones) and then applied to organic or inorganic substrates by brushing, dipping, padding, soaking, spraying, fogging or by using foam finishing techniques to give a final treatment of 0.1 to 1.0 percent by weight active ingredient.

After applying the antimicrobial agent, the substrate can then be dried at temperatures from ambient to a maximum of 160° C (320° F) to effect complete condensation of silanol groups and to remove water, solvents and/or traces of methanol from hydrolysis. Optimum application and drying conditions, such as time and temperature, should be determined for each application before use.

EPA REGISTRATION REQUIREMENTS

The applications for which this product are used require approval by the Environmental Protection Agency on an end-use basis in regard to claims made thereof. Formulators are responsible for satisfying registration requirements for their products.

PRECAUTIONARY STATEMENTS

Corrosive. Causes irreversible eye damage. May be fatal if swallowed. Causes skin irritation. Harmful if absorbed through skin or inhaled. Harmful if inhaled. Avoid contact with skin, eyes, or clothing. Avoid breathing vapor. Wear protective clothing and gloves, and protective eyewear (goggles and face shield). Wash thoroughly with soap and water after handling and before eating, drinking, using tobacco, or using the toilet. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark; this product might be toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

AM 500 I, by standard biological oxygen demand (BOD) and total oxygen demand (TQD) petermination, does not appear to be biodegradable. Potential harm to the environment is minimized, nowever, because of the minimal amount of chemical applied and its durable coupling to surfaces.

Inactivation of solutions containing AM 500 I may be accomplished by one of the following methods:

- addition of an anionic surfactant or detergent in quantity equivalent to that of AM 500 l in solution; or
- addition of Triton X-100 nonionic detergent at a final concentration of 10,000 ppm (1.0 percent volume/volume) or greater to bath solutions up to 1.0 percent volume/volume of AM 500 I.

Every effort should be made to contain accidental spills of AM 500 I to the immediate area. This may be accomplished by the use of sandbags to confine the spill to facilitate cleanup and disposal. Contaminated sand may then be disposed of by burial in an approved landfill. Many spills may be cleaned up with rags by wiping and/or mopping and allowing the liquid to absorb into the fabric. The rags may then be disposed of by incineration.

Floor drains in areas of material use should be protected with sandbags to contain accidental spills.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in original, unopened containers below 3°C (86°F) and above 0°C (32°F). AM 500 I has a minimum shelf life of 12 months from the date of shipment from BioShield.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Before handling, read product label in its entirety

IMPORTANT: WARRANTY AND DISCLAIMER INFORMATION

BioShield Technologies, Inc., warrants that the product conforms to its chemical description and is reasonably fit for the purposes stated in this bulletin when used in accordance with directions under normal conditions of use; but this warranty of fitness for a particular purpose does not extend to the use of this product contrary to bulletin instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to seller, and buyer assumes the risk of any such use.

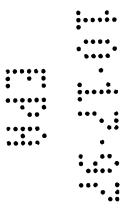
BIOSHIELD SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING THE WARRANTY OF MERCHANTABILITY.

REFERENCES

- 1. Hough, J.S. and T.P. Lyons. "Coupling of Enzymes On a Microorganisms" *Nature*. London, 1972, 235-289.
- 2. Johannsen, O.K., F.O. Stark, G.E. Vogel and R.M. Fleishmann. "Evidence for Chemical Bona Formation at Silane Coupling Agent Interfaces." *J. Compos. Mater.*, 1967, 1:278-292.
- 3. Plueddemann, I.P. "Adhesion Through Silane Coupling Agents." J. Adhesion, 1970, 2:184-201...
- 4. Venter, J.E., J.E. Dixon, P.R. Maroko and N.O. Kaplan. "Biologically Active Catacholamine Covalently Bound to Glass Bead." *Proc. Nat. Acad. Sci.* (U.S.A.). 1972, 69:1141-1145.
- 5. Weetall, H.H. "Trypsin and Papain Covalently Coupling to Porous Glass." Science, 1969, 166.615, 617.
- 6. Isquith, A.J., E.A. Abbott and P.A. Walters. "Surface-Bonded Antimicrobial Activity of an Organosilicon Ammonium Chloride." *Appl. Microbial.*, 1972, 24:859-863.
- 7. Gettings, R.L. and B.L. Triplett. "New Durable Antimicrobial Finish for Textiles." AATCC Book of Papers—1978 Nat. Tech. Conf., 1978, 259-261.

- 8. Isquith, A.J. and C.J. McCallum. "Surface Kinetic Test Method for Determining Rate of Kill by an Antimicrobial Solid." *Appl. & Environ. Microbial.*, 1978, 36:700-704.
- 9. Malek, J.R. and J.L. Speier. "Development of an Organosilicone Antimicrobial Agent for the Treatment of Surfaces." *J. Coated Fabrics*, 1992, 12:38-45.
- 10. Speier, J.L. and J.R. Malek. "Destruction of Microorganisms by Contact With Solid Surfaces." *J. Colloid Interface Science*, 1982,89-68-76.
- 11. Siddiqui, W.H., J.R. Malek, E. Stanton and E. J. Hobbs. "Percutaneous Absorption of an Antimicrobial Organosilicon Quaternary Ammonium Chloride in Rabbits." J. Appl. Toxicol., 1983, 3.3:146-149.
- 12. McGee, J.G., J.R. Malek and W.C. White. "New Antimicrobial Treatment for Carpet Applications." *Am. Dyestuff Rep.*, 1983, 6:56-59.
- 13. Hales M.G., M.E. Sorkin and W.C. White. "Antimicrobial Treatments, Part I: What They are and Why They Are Used." *Cleaning and Restoration.*" 1986, March, 14-15.
- 14. Hales, M.G., M.E. Sorkin and W.C. White. "Antimicrobial Treatments, Part II: Types and Considerations for Use." *Cleaning and Restoration*", 1986, Vol. 24, Num. 4, 13-15.
- 15. Hales, M.G. and W.C. White. "Antimicrobial Treatments, Part III: Methods for Determining Their Effectiveness." Cleaning and Restoration", 1986. May, 18-20.
- 16.Battice, D.R. and M.G. Hales. "A New Technology for Producing Stabilized Foams Having Antimicrobial Activity." *Journal of Cellular Plastics*, 1985, Vol. 21, Num. 5, 332-337.

BioShield Technologies, Inc. 4405 International Boulevard, Suite B109 Norcross, GA 30093



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DEC 1 8 1997

Jellinek, Schwartz & Connolly, Inc. 1525 Wilson Blvd., Suite 600 Arlington, VA 22209

ATTN: Blane Dahl, Registration Manager

SUBJECT: BIOSHIELD AM 500 I

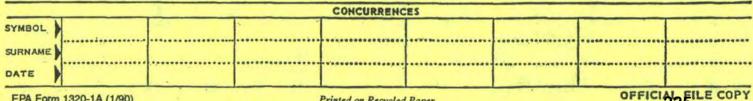
EPA File Symbol 70871-E

Application Dated August 15, 1997

Dear Mr. Blane:

- * The Confidential Statement of Formula dated August 15, 1997 for AM 500 I, is in compliance with PR Notice 95-2, and concurs with the label. The CSF is acceptable.
- *The Product Chemistry for the following Guideline Reference Numbers have been satisfied and are in compliance with 40CFR part 158.155-158.190;
 - 62-1 -Preliminary Analysis
 - 62-2 -Certification of the Ingredient Limits
 - 62-3 Analytical Methods to Verify Certified Limits
- * Storage and stability studies are still required to satisfy Series 63 Product Chemistry (63-17) requirements. This product cannot be registered until all Product Chemistry requirements are met.

If you have any further questions, please contact Ms. Barbara Pringle at (703)308-6236.



EPA Form 1320-1A (1/90)

Printed on Recycled Paper

OFFICIAL FILE COPY

Sincerely,

Velma Noble

Team Leader 31

Regulatory Management Branch I Antimicrobials Division

SUBJECT: PRODUCT CHEMISTRY REVIEW OF:

DP Bar-code: D238628 Reg. No. or File Symbol: 70871-E

Manufacturing-Use [] OR End-Use Product - [X]

TO: Barbara Pringle

PM Team No. - 31

FROM: Wanda Jakob, Biologist Wanda Jakof 10-06-97

Risk Assessment and Science Support Branch, Team 3

Antimicrobials Division (7510W)

THRU: Laura Morris, Acting Team Leader Laura Morris

Risk Assessment and Science Support Branch, Team 3

Antimicrobials Division (7510W)

SUMMARY OF INFORMATION REVIEWED AND FINDINGS

The Confidential Statement of Formula dated 08-15-97 for AM 500 I, is in compliance with PR Notice 95-2, and concurs with the label. The CSF is accepted.

The Product Chemistry Data for the following Guideline Reference Numbers have been satisfied and are in compliance with 40 CFR part 158.155-158.190;

62-1 - Preliminary Analysis

62-2 - Certification of the Ingredient Limits

62-3 - Analytical Methods to Verify Certified Limits

Storage and stability studies are still required to satisfy Series 63 Product Chemistry (63-17) requirements.

BioShield Technologies, Inc.

*4405 International Boulevard, Suite B109 Norcross, GA 30093

BioShield AM 500 I

ANTI-MICROBIAL AGENT & PROTECTANT

A Silicone Quaternary Ammonium Salt (For Manufacturing Use Only)

92.0% 100.0% 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride...... Active Ingredient: Inert Ingredients:

KEEP OUT OF REACH OF CHILDREN DANGER

Lot No. EPA Reg. No. xxxx-xx

EPA EST. xxxxx-GA-xx

NET CONTENTS: 8 oz., 1 gal., 5 gal., or 55 gal.

STATEMENT OF PRACTICAL TREATMENT

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.

person. Drink promptly a large quantity of milk, eggwhites, gelatin solution, or, if these are not available, drink large quantities of IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious water. Avoid alcohol.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

and protective eyewear (goggles and face shield). Wash thoroughly with soap and water after handling and before eating, drinking, inhaled. Harmful if inhaled. Avoid contact with skin, eyes, or clothing. Avoid breathing vapor. Wear protective clothing and gloves, Corrosive. Causes irreversible eye damage. May be fatal if swallowed. Causes skin irritation. Harmful if absorbed through skin or using tobacco, or using the toilet. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in

De-activation of AM 500 I can be achieved by the addition of anionic surfactant in quantity equivalent to that of AM 500 I.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

SEE COLLATERAL LABEL FOR COMPLETE USE DIRECTIONS

NOTE: This product should not be used or compounded with any bleach or oxidizing agents. Do not use in conjunction with anionic surfactants

For formulating use into end-use products listed in the attached "Information About Antimicrobial Agents" pamphlet.

APPROVED USES

AM 500 I is approved for use in formulating disinfectants, sanitizers and microbiocides for use in laundry additives, carpet treatment products, upholstery and drapery treatment products, and building cleaning and treatment products.

AM 500 can be used to impart durable, broad-spectrum, antimicrobial protection to substrates for the following applications:

- Air filters for furnaces, air-conditioners, air purification devices, automobiles, recirculating air handling systems;
 - Air filters/materials;
- Aquarium filter material;
- Bed sheets, blankets, and bedspreads;

- Buffer pads (abrasive and polishing);
- Carpets and draperies;
- Fiberfill for upholstery, sleeping bags, apparel, etc., where the fiber is cotton, natural down, nylon, polyester, rayon, or wool;
 - Fiberglass ductboard;
- Fire hose fabric;
 - . Humidifier belts;
- Mattress pads and ticking;
- Men's underwear and outerwear;
- Non-woven disposable diapers;
- Non-woven polyester;
- Outerwear apparel;
- Disposable polyurethane foam cushions for Lapidus Airfloat Systems;
- Polyurethane foam for household, industrial, and institutional sponges and mops;
- Polyurethane and polyethylene foam, when covered;
- Polyurethane foam for packaging and cushioning in non-food contact applications;
 - Polyurethane foam used as a growth medium for non-food crops and plants;
- Pre-moistened towelettes and tissue wipes (these do not impart pesticidal properties);
- Roofing materials defined as shingles, roofing granules, wood shakes, felt, stone and synthetic overcoats;
 - Sand bags, tents, tarpaulins, sails, and ropes;
 - Athletic and casual shoes;
- Shoe insoles;
- Shower curtains;
- wool/acrylic/nylon/Lycra; provides residual self-sanitizing activity against athlete's foot fungus (Trichophyton mentagrophytes) on the sock, Socks comprised of nylon, nylon/orlon, cotton/nylon, linen/Lycra, acrylic/polypropylene/nylon/Lycra, wool/silk/nylon/Lycra and durable for up to 10 repeated washings; prevents 99.9 percent of the growth of athlete's foot fungus on the sock;
 - Throw rugs;
- Toweling made of 100 percent cotton, 100 percent polyester, and blends of the two fibers;
- Toilet tank and seat covers;
- Umbrellas;
- Upholstery made of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polyolefins, polypropylene, rayon, spandex, vinyl, and wool;
- Vacuum cleaner bags and filters;
- Vinyl paper-wallpaper for non-food contact surfaces;
- Disposable wiping cloths that can be used for multiple purposes such as dusting or washing furniture, cars, walls, windows, floors, appliances, dishes, counter tops, etc.; the wiping cloths do not impart pesticide properties;
 - Women's hosiery; and
- Women's intimate apparel.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

inaccessible to children and away from food or feed. AM 500 I has a minimum shelf life of 12 months from the date of shipment Pesticide Storage: Store in original, tightly closed containers below 30°C (86°F) and above 0°C (32°F) in a secure area from BioShield.

violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

FOR MORE INFORMATION CONCERNING THIS PRODUCT, PLEASE CONSULT THE MATERIAL SAFETY DATA SHEET (MSDS). THE MSDS CAN BE OBTAINED BY WRITING BIOSHIELD TECHNOLOGIES, INC. AT 4405 INTERNATIONAL BOULEVARD, SUITE B109, NORCROSS, GEORGIA, 30093.

COLLATERAL LABELING

BioShield Technologies, Inc.

4405 International Boulevard, Suite B109 Norcross, GA 30093

Information About Antimicrobial Agents

TYPICAL PROPERTIES

These values are not intended for use in preparing specifications

	CH₃
Structure	.[(CH ₃ O) ₃ Si(CH ₂) ₃ N-C ₁₈ H ₃₇] ⁺ Cl
	CH₃
Concentration	5.0%
Appearance	Colorless liquid
Solubility	Miscible in all proportions with water, ethanol, and methanol
Thermal Stability °C (°F)	Stable to 30°C (86°F)

Specification Writers: Please contact BioShield for information regarding specifications

DESCRIPTION

AM 500 I is BioShield's designation for 3-(trimethoxysilyI) propyloctadecyldimethyl ammonium chloride containing 5 percent active ingredient by weight. Alkoxysilanes of this nature have been shown to form durable bonded coatings to a number of materials (see "References" section).

AM 500 I offers users the following features:

- Good durability—BIOSHIELD AM 500 I Antimicrobial Agent imparts durable, broad-spectrum, biostatic activity to the surface of a wide variety of substrates; it is leach-resistant and nonmigrating and is not consumed by microorganisms.
- Broad-spectrum activity—effective against gram positive and gram negative bacteria, fungi, algae and yeasts; antimicrobial action is exhibited on contact.
- Increased efficiency—through proper application, durable bacteriostatic, fungistatic and algistatic surfaces can be attained with a minimum amount of AM 500 I.

BENEFITS

The following benefits are derived when a formulation containing the active ingredient is applied to a surface:

- Provides hygienic freshness and combats deterioration caused by bacteria, fungi, algae, and yeasts.
- Inhibits growth of bacteria and mildew on the treated article.
- Prolongs the life of a article by inhibiting the growth of bacteria and mildew.
- Provides a durable, residual, antimicrobial treatment that is not destroyed by repeated cleaning.
- Delete

- Resists development of bacterial and fungal odors.
- Retains freshness by resisting the growth of odor-causing bacteria and mildew (fungus).
- Provides a chemical treatment that enables fabrics to resist odors.
- Provides a unique chemical treatment that resists mildew and bacteria growth and imparts odor resistance:
- Contains no phenols, tin, heavy metals, lead, mercury, or formaldehyde.
- Product performance with little degradation up to 375°F.

Materials treated with formulations containing the antimicrobial agent AM 500 I are preserved by the bacteriostatic, fungistatic and algistatic action imparted by the active ingredient. AM 500 I inhibits the growth of microorganisms that are responsible for causing odor, discoloration and deterioration. It also provides residual inhibition of microorganisms to aid in the control of these deleterious effects. AM 500 I forms a coating on a wide variety of substrates and antimicrobial action is exhibited on contact.

APPROVED USES

AM 500 I is approved for use in formulating disinfectants, sanitizers and microbiocides for use in laundry additives, carpet treatment products, upholstery and drapery treatment products, and building cleaning and treatment products.

AM 500 can be used to impart durable, broad-spectrum, antimicrobial protection to substrates for the following applications:

- Air filters for furnaces, air-conditioners, air purification devices, automobiles, recirculating air handling systems;
- Air filters/materials;
- · Aquarium filter material;
- · Bed sheets, blankets, and bedspreads;
- Buffer pads (abrasive and polishing);
- · Carpets and draperies;
- Fiberfill for upholstery, sleeping bags, apparel, etc., where the fiber is cotton, natural down, nylon, polyester, rayon, or wool;
- Fiberglass ductboard;
- Fire hose fabric;
- Humidifier belts;
- Mattress pads and ticking:
- Men's underwear and outerwear:
- Non-woven disposable diapers;
- Non-woven polyester;
- Outerwear apparel;
- Disposable polyurethane foam cushions for Lapidus Airfloat Systems;
- Polyurethane foam for household, industrial, and institutional sponges and mops;
- Polyurethane and polyethylene foam, when covered;
- Polyurethane foam for packaging and cushioning in non-food contact applications:
- Polyurethane foam used as a growth medium for non-food crops and plants;
- Pre-moistened towelettes and tissue wipes (these do not impart pesticidal properties):
- Roofing materials defined as shingles, roofing granules, wood shakes, felt, stone and synthetic overcoats:
- Sand bags, tents, tarpaulins, sails, and ropes;
- Athletic and casual shoes;
- Shoe insoles:
- Shower curtains:
- Socks comprised of nylon, nylon/orlon, cotton/nylon, linen/Lycra, acrylic/polypropylene/nylon/Lycra, wool/silk/nylon/Lycra and wool/acrylic/nylon/Lycra; provides residual self-sanitizing activity against athlete's foot fungus (*Trichophyton mentagrophytes*) on the sock, durable for up to 10 repeated washings; prevents 99.9 percent of the growth of athlete's foot fungus on the sock;
- Throw rugs:
- Toweling made of 100 percent cotton, 100 percent polyester, and blends of the two fibers;
- Toilet tank and seat covers;
- Umbrellas;
- Upholstery made of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polyolefins, polypropylene, rayon, spandex, vinyl, and wool;
- Vacuum cleaner bags and filters;
- Vinyl paper-wallpaper for non-food contact surfaces;
- Disposable wiping cloths that can be used for multiple purposes such as dusting or washing furniture, cars, walls, windows, floors, appliances, dishes, counter tops, etc.; the wiping cloths do not impart pesticide properties;
- Women's hosiery; and
- Women's intimate apparel.

DIRECTIONS FOR USE

AM 500 I can be incorporated directly into formulations used to make the end products listed in this bulletin.

AM 500 I can also be diluted with water or other solvents (for example, alcohol, and ketones) and then applied to organic or inorganic substrates by brushing, dipping, padding, soaking, spraying, fogging or by using foam finishing techniques to give a final treatment of 0.1 to 1.0 percent by weight active ingredient.

After applying the antimicrobial agent, the substrate can then be dried at temperatures from ambient to a maximum of 160° C (320° F) to effect complete condensation of silanol groups and to remove water, solvents and/or traces of methanol from hydrolysis. Optimum application and drying conditions, such as time and temperature, should be determined for each application before use.

EPA REGISTRATION REQUIREMENTS

The applications for which this product are used require approval by the Environmental Protection Agency on an end-use basis in regard to claims made thereof. Formulators are responsible for satisfying registration requirements for their products.

PRECAUTIONARY STATEMENTS

Corrosive. Causes irreversible eye damage. May be fatal if swallowed. Causes skin irritation. Harmful if absorbed through skin or inhaled. Harmful if inhaled. Avoid contact with skin, eyes, or clothing. Avoid breathing vapor. Wear protective clothing and gloves, and protective eyewear (goggles and face shield). Wash thoroughly with soap and water after handling and before eating, drinking, using tobacco, or using the toilet. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark; this product might be toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

AM 500 I, by standard biological oxygen demand (BOD) and total oxygen demand (TOD) determination, does not appear to be biodegradable. Potential harm to the environment is minimized, however, because of the minimal amount of chemical applied and its durable coupling to surfaces.

Inactivation of solutions containing AM 500 I may be accomplished by one of the following methods:

- addition of an anionic surfactant or detergent in quantity equivalent to that of AM 500 I in solution; or
- addition of Triton X-100 nonionic detergent at a final concentration of 10,000 ppm (1.0 percent volume/volume) or greater to bath solutions up to 1.0 percent volume/volume of AM 500 I.

Every effort should be made to contain accidental spills of AM 500 I to the immediate area. This may be accomplished by the use of sandbags to confine the spill to facilitate cleanup and disposal. Contaminated sand may then be disposed of by burial in an approved landfill. Many spills may be cleaned up with rags by wiping and/or mopping and allowing the liquid to absorb into the fabric. The rags may then be disposed of by incineration.

Floor drains in areas of material use should be protected with sandbags to contain accidental spills.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in original, unopened containers below 3°C (86°F) and above 0°C (32°F). AM 500 I has a minimum shelf life of 12 months from the date of shipment from BioShield.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Before handling, read product label in its entirety

IMPORTANT: WARRANTY AND DISCLAIMER INFORMATION

BioShield Technologies, Inc., warrants that the product conforms to its chemical description and is reasonably fit for the purposes stated in this bulletin when used in accordance with directions under normal conditions of use; but this warranty of fitness for a particular purpose does not extend to the use of this product contrary to bulletin instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to seller, and buyer assumes the risk of any such use.

BIOSHIELD SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING THE WARRANTY OF MERCHANTABILITY.

REFERENCES

- 1. Hough, J.S. and T.P. Lyons. "Coupling of Enzymes On a Microorganisms" *Nature*. London, 1972, 235-289.
- 2. Johannsen, O.K., F.O. Stark, G.E. Vogel and R.M. Fleishmann. "Evidence for Chemical Bona Formation at Silane Coupling Agent Interfaces." *J. Compos. Mater.*, 1967, 1:278-292.
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- 8. Isquith, A.J. and C.J. McCallum. "Surface Kinetic Test Method for Determining Rate of Kill by an Antimicrobial Solid." *Appl. & Environ. Microbial.*, 1978, 36:700-704.
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BioShield Technologies, Inc. 4405 International Boulevard, Suite B109 Norcross, GA 30093

Reviewer ID Submission No. Data Package No. COOKS FOR APPLICATIONS FOR PECISTRATION/AMENDMENTS Action Code 187 File Symbol/Reg. No. $7087-E \approx 31$ | 10 Descriptor (Amend/Resultations only) |5 | Intrastate Call-in / / (Y) Yes | 15 | Child-resistant / /(C) Certification Packaging / (N) NO / /(\$) Service Person |20| Registration Type: / (R) Non-residential Use Only // (1) Conditional / / (2) Unconditional (N) Not-Applicable 125 Proposed Classification: 130 Final Classification: / / (R) Restricted / / (R) Restricted / / (G) General (N) Not Classified |35| Date on Application: |04| EPA Received Date: |40| Date Received by PH |80| Method of Support: / / (1) Cite-All / (6) Owner Submission / (7) Total Submission $\sqrt{-/}$ (4) Not Applicable / (8) Selective Method / / (5) Not Submitted RESPONSE WE. STAD RESPONSE DATE RETURNED SENT 3000 Reviewers Requested: STAC CH EF PL DEB NDEB 73 EEB **EFGB** 122 Response 1115 FINAL Response ACTION Code 75-DAY RESPONSE DUE DATE: / /(Y) Yes / /(N) NO

DP BARCODE: D240665

SUBMISSION: S532436

DATA PACKAGE RECORD

BEAN SHEET

DATE: 11/10/97

Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION

ACTION: 187 RESB AmD-OC-MINOR CHG

CHEMICALS: 107401 3-(Trimethoxysilyl) propyl dimethyl octadecyl ammon 5.0000%

ID#: 070871-R BIOSHIELD AM 500

COMPANY: 070871 BIOSHIELD TECHNOLOGIES, INC

PRODUCT MANAGER: 31 VELMA NOBLE 703-305-6233 ROOM: CM2 1 VELMA NOBLE BARBARA PRINGLE 268 PM TEAM REVIEWER: 703-305-6484 ROOM: CM2 280

RECEIVED DATE: 10/10/97 DUE OUT DATE: 02/07/98

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 240665 EXPEDITE: N DATE SENT: 11/10/97 DATE RET.: / / CHEMICAL: 107401 3-(Trimethoxysilyl) propyl dimethyl octadecyl ammonium chlor

DP TYPE: 001

DIV : AD

BRAN: RASSB

CSF: N LABEL: Y

DATE IN DATE OUT ASSIGNED TO

Chaminstry

10/10/97 11/13/97

ADMIN DUE DATE: 02/13/98

NEGOT DATE: / / PROJ DATE:

SECT: RASSB2 REVR :

CONTR:

* * * DATA REVIEW INSTRUCTIONS * * *

Review and clarify agent's letter about uses of product.

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

BRANCH/SECTION DATE OUT DUE BACK INS CSF LABEL

239

DP BARCODE: D240666

CASE: 061695

DATA PACKAGE RECORD

SUBMISSION: S532438

BEAN SHEET

DATE: 11/10/97

Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

ACTION: 187 RESB AmD-OC-MINOR CHG CASE TYPE: REGISTRATION

CHEMICALS: 107401 3-(Trimethoxysilyl) propyl dimethyl octadecyl ammon 5.0000%

ID#: 070871-E BIOSHIELD AM 500 I

COMPANY: 070871 BIOSHIELD TECHNOLOGIES, INC

PRODUCT MANAGER: 31 VELMA NOBLE
PM TEAM REVIEWER: BARBARA PRINGLE 703-305-6233 ROOM: CM2 268 703-305-6484 ROOM: CM2 280

RECEIVED DATE: 10/10/97 DUE OUT DATE: 02/07/98

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 240666 EXPEDITE: N DATE SENT: 11/10/97 DATE RET.: CHEMICAL: 107401 3-(Trimethoxysilyl) propyl dimethyl octadecyl ammonium chlor

LABEL: Y CSF: N

N DATE IN ASSIGNED TO 10/10/97 DIV : AD

BRAN: RASSB
SECT: RASSB3
REVR: Blackwell 1/33/98

REVR: Blackwell CONTR:

ADMIN DUE DATE: 02/13/98

DATE OUT ADMIN DUE DATE: U2/13/3

* * * DATA REVIEW INSTRUCTIONS * *

Review same as for 70871-R

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DATE OUT DUE BACK 11/10/97 02/13/98 BRANCH/SECTION INS CSF LABEL Y 240669 / RASSB/RASSB2

See yellow highlighted paragraph on PZ of Jellinek cover lette for IAN's comments

We still need eye mitation

eff of Michele

Jellinek, Schwartz & Connolly, Inc.

1525 Wilson Boulevard, Suite 600 Arlington, VA 22209 (703) 527-1670 • Fax: (703) 527-5477



Hand Delivered

Consultants in Environmental Science, Policy & Management

October 15, 1997

Ms. Velma Noble (Acting PM 31)
Regulatory Management Branch I
Antimicrobials Division (7510W)
Office of Pesticide Programs
U. S. Environmental Protection Agency
Document Processing Desk
Room 266A, Crystal Mall 2
Arlington, VA 22202

Re: Response to EPA's September 5, 1997, and October 10, 1997, Letters BioShield AM 500 and AM 500 I (EPA File Symbols 70871-R and -E)

Dear Ms. Noble:

Thank you for your letters dated September 5, 1997, and October 10, 1997, regarding the registration applications for BioShield AM 500 and AM 500 I (EPA File Symbols 70871-R and -E, respectively). On behalf of BioShield Technologies, Inc. (BioShield; 4405 International Boulevard, Suite B109, Norcross, Georgia, 30093; EPA Company Number 70871), we are responding to your letters, and submitting materials in support of BioShield's registration applications.

Acute Toxicology

We understand from EPA's September 2, 1997, acute toxicology review that the acute toxicology waiver requests for BioShield AM 500 and AM 500 I were acceptable for all acute toxicology studies except the primary eye irritation study (Guideline Number 81-4). EPA believes that the proposed precautionary language on the draft product labels significantly overstates the risk of the product; thus, EPA is requesting that a primary eye irritation study be submitted prior to registration of these two products.

Since the overstatement of the risk of the BioShield AM 500 and AM 500 I products will not increase any hazards to human health, but rather ensures that the proposed product is used with caution, we propose that EPA grant conditional registrations of BioShield AM 500 and AM 500 I. Such registrations would be based on the condition that BioShield conduct a primary eye irritation study. BioShield proposes to submit the results of this study to EPA by June 30, 1998, and, at that time, request appropriate, revised precautionary language for these products.

Efficacy Data Requirements

We understand from your September 5, 1997, letter that BioShield needs to clarify the efficacy claims on the AM 500 and AM 500 I product labels in order to determine what efficacy data will be required for registration of the products. We believe the information in this letter along with the following items will address these concerns:

- an application form (EPA Form 8570-1);
- · five copies of the revised product label;
- one copy of the revised product label with the revisions highlighted;
- a Certification with Respect to Citation of Data form (EPA Form 8570-29);
- a data matrix; and
- a letter from Aegis Environmental Management Inc. (Aegis) regarding MRID Number 164909.

In order to clarify the efficacy claims and target pests for the AM 500 and AM 500 I products, the following section was added to the draft product labels and collateral labeling under the "Approved Uses" heading:

"Target Pests: The active ingredient in AM 500 I is effective against gram positive and gram negative bacteria, fungi (including mold and mildew), algae, and yeasts. The following species have been tested: Salmonella choleraesius, Staphylococcus aureas, Pseudomonas aeruginosa, Streptococcus faecalis, Eschericia coli, Asperillus niger, and Trichophyton interdigitale."

In addition, the following label revisions were made to the draft product labels and collateral labeling.

 The statement "...and air treatment products" was added to the first paragraph under the Approved Uses heading.



- The statement "AM 500 [I] can be used for incorporation into and treatment of the
 following items or substrates to impart durable, broad-spectrum, antimicrobial
 protection:" replaced the statement "AM 500 [I] can be used to impart durable,
 broad-spectrum, antimicrobial protection to substrates for the following
 applications:" in order to clarify the uses of the product.
- The following uses were added to the list in the Approved Uses section of the labels and collateral labeling: building materials; concrete and materials used to make concrete; fibers, such as polypropylene fibers and fabrics made from those fibers; fibers, such as polypropylene fibers and fabrics made from those fibers for incorporation into concrete, and pool and spa filters.

We understand that additional data may be required to support BioShield's efficacy claims and the specific target pests. Thus, we are citing MRID number 164909, a study titled "Physical and Chemical Properties [of Dow Corning X9-5700]," in support of the use sites and claims listed on the BioShield AM 500 and AM 500 I product labels. Although this study is titled "Physical and Chemical Properties" and is coded as such when located in the National Pesticide Information Retrieval System, it also includes several efficacy studies for Dow Corning products and product dilutions containing the same active ingredient as the AM 500 and AM 500 I products (please see the enclosed letter from Aegis). We understand that this study was reviewed and accepted by EPA.

Product Chemistry

BioShield submitted Series 62 product chemistry data to the Agency on August 15, 1997 (MRID # 44351901). These data included the Preliminary Analysis (Guideline Number 62-1), the Certification of Ingredient Limits (Guideline Number 62-2), and an Analytical Method for Enforcement of Limits (Guideline Number 62-3) (MRID Number 44351901). Please note that storage stability studies (Guideline Number 63-17) for AM 500 and AM 500 I, including the formulations containing the alternate were initiated on June 27, 1997, at Springborn Laboratories, Inc., in Wareham, Massachusetts. We will submit these data as soon as they become available.

As you requested in your October 10, 1997, letter, attached please find a revised Confidential Statement of Formula (CSF) for AM 500 (EPA File Symbol 70871-R) that lists all of the ingredients in the product. I understand that Kimberly Lowe of Jellinek, Schwartz & Connolly, Inc., discussed the requested revisions with Barbara Pringle of your office. This revised CSF provides a complete chemical identity of the proposed product.

Inert ingredient information may be entitled to confidential treatment



If you have any questions about this application, please contact me at (703) 312-8531 or Kimberly Lowe at (703) 312-8539.

Sincerely,

Blane Dahl

Registration Manager

Jellinek, Schwartz & Connolly, Inc.

Authorized Representative of

BioShield Technologies, Inc.

Enclosures

c: Joachim Berkner, BioShield Technologies, Inc.



Jellinek, Schwartz & Connolly, Inc.

1525 Wilson Boulevard, Suite 600 Arlington, VA 22209 (703) 527-1670 • Fax: (703) 527-5477



Hand Delivered

Consultants in Environmental Science, Policy & Management

October 15, 1997

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Antimicrobials Division (7510W)
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Sincerely,

Blane Dahl

Registration Manager

Jellinek, Schwartz & Connolly, Inc.

Authorized Representative of

BioShield Technologies, Inc.

Enclosures

c: Joachim Berkner, BioShield Technologies, Inc.

Please read instructions on reverse before completing form.		Form Appro	ved. OMB No. 2070-0060 Approval Expires 5-31-98
United States		Registration	OPP Identifier Number
EPA Environmental Protec	tion Agency	Amendmer	nt
Washington, DC 20	460	Other	
Applicat	ion for Pesticide	- Section I	
1. Company/Product Number	2. EPA	A Product Manager	3. Proposed Classification
70871- E 4. Company/Product (Name)	PM#	Velma Noble	
BioShield AM 500 I		31	None Restricted
5. Name and Address of Applicant (Include ZIP Code) BioShield Technologies, Inc.			cordance with FIFRA Section 3 (c) (3)
4405 International Boulevard, Suite B109	to:		ntical in composition and labeling
Norcross, GA 30093	EPA	Reg. No	
Check if this is a new address	Produ	uct Name	
	Section - II		
Amendment - Explain below.		Final printed labels in resp	onse to
Resubmission in response to Agency letter dated 9/5/97 a	nd 10/10/97	"Me Too" Application.	
Notification - Explain below.		Other - Explain below.	
Explanation: Use additional Page(s) if necessary. (For section	ion I and Section II)		
Submission of information in response to Age	ncy letters dated Se	entember 5. 1997, ar	nd October 10, 1997
Outilisation of information in teaponed to 1.35	lloy lottoro datou	ptombor of reer,	iu Ooloboi 10, 1001
	Castian III	<u></u>	
Material This Product Will Be Packaged In:	Section - III		
Unit Packaging	Water	Soluble Packaging	2. Type of Container
Child-Resistant Packaging Yes	<u> </u>	Yes	Metal
Yes*	🔲	No	☐ Plastic ☐ Glass
No If "Yes"	No. per If "Yes" Container Unit Pa		· I □ Barrar
* Certification must Unit Packaging wgt.	Container Unit Pa	ackage wgt. Containe	Other (Specify)
be submitted 3. Location of Net Contents Information 4. Siz.	te(s) Retail Container		hel Directions
4. SE	e(3) Netali Containe	On Label	Directions
Label Container		1 =	ng accompanying product
Manner in Which Label is Affixed to Product	Lithograph		No. 1975 - 1975
	Paper glued	Other	
	Stenciled		
	Section - IV		
Contact Point (Complete items directly below for identification Name	n of individual to be contacted Title Registration Mana		this application.) • • • • • • elephone No. (Include Area Code)
Blane Dahl	Schwartz & Connolly, I Representative of BioS	Inc., Authorized [('	703) 312-8531
Certifi	Technologies, Inc.		6. Date Application
I certify that the statements which I have made on this form	and all attachments are true		Received
I acknowledge that any knowingly false or misleading statem both under applicable law.	nent may be punishable by f	fine or imprisonment or	(Stamped)
2. Signature	3. Title		•
Ble Dare		ellinek, Schwartz & Conn ive of BioShield Technolo	
4. Typed Name Blane Dahl	5. Date October 15, 1997		···.:

EPA

United States

Environmental Protection Agency Washington, DC 20460

Form Approved

OMB No. 2070-0060 Approval Expires 05-31-95

Certification with Res	pect to Citation of Data	_ Approvar Expires 00-01-00
Applicants Name and Address BioShield Technologies, Inc. 4405 International Boulevard, Suite B109 Norcross, GA 30093	EPA File Symbol/Registration Number 70871-E	
Noticioss, GA 30093	Product Name BioShield AM 500 I	
	Date of Application May 14, 1997	
NOTE TO 1		
NOTE: If your product is a 100% repackaging of anot for the same uses, you do not need to submit this form. Form 8570-27). 1. This application is supported by all data submitted indicated, this application is supported by all data in product that is identical or substantially similar and submitted if this application sought the initial regist uses under the data requirements in effect on the da items 2 and 3, or 4 below that pertain to your applications 2 and 3, or 4 below that pertain to your applications 2 and 3, or 4 below that pertain to your applications 2 and 3, or 4 below that pertain to your applications 2 and 3, or 4 below that pertain to your applications 2 and 3, or 4 below that pertain to your applications 2 and 3, or 4 below that pertain to your applications 3. I certify that, for each study cited in support of the animal of companies 3. I certify that for each study cited in in support of the animal submitter*; or I have obtained the written permission of the which is Aegis Environmental Management Incompanies 3 submitters with the appropriate chemical names of companies)	You must submit the Formulator's Exemple or cited in the application. In addition, in the Agency's files that concern the properthat is one of the types of data that would tration of a product of identical or similar te of approval of this application. (Check cation.) Is application for registration that is an exemple original submitter for	f cite-all options are erties or effects of this d be required to be composition and intended a the appropriate boxes, in clusive use study.
b. I have obtained in writing the companies	for	that
	this application and have offered to: (a) (1)(F) and 3(c)(2)(D) of the Federal Insect ce negotiations to determine which data a ne amount and terms of compensation due	Pay compensation for icide, Fungicide and re subject to the
Companies for	(for multiple	•••••
chemicals link the companies who are the collisted on the Pesticide Data Submitters List method or cite-all option under Selective M. Companies for for (insert names of companies) chemicals link the companies who are the companies which I have submitted the studies which I have	for all active ingredients contained in my lethod*). (Also, sign the General Offer 3 (for multiple (insert name of chemical) original data submitters with the appropria	y product (cite-all tatement below.)
4. I certify that for each study cited in support of the obtain written permission because all time periods		
* A Data Matain identifying the and displayment.	(Note: a Data Matricia and anning 1	lor the site of matter 1
	Blane Dahl, Jellinek, Schwartz & Connolly, Inc.,	Date
Size January Authorized Repre	esentative of BioShield Technologies, Inc. to pay compensation to other persons, with regard to	October 15, 1997
the approval of this application, to the extent required. Signature Name and Title		Date
		<u>, . =++</u>

DATA REQUIREMENT LISTING

			TUA			DATE									
PRODUCT NAME: BioShield AM 500 I	ME: 00 I		EPA REG	EPA REG. NO. OR FILE SYMBOL: 70871-E	SYMBOL:		FORMULATOR EXEMPTION ASSERTED: Yes)R EX	EMPI Yes	ION /	ASSE	RTED			
APPLICANT'S NAME AND BioShield Technologies, Inc.	APPLICANT'S NAME AND ADDRESS: BioShield Technologies, Inc.	GA 30003	AP	APPLICATION DATE:	VTE:	3-(tri	NAME OF ACTIVE INGREDIENT: 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride	F ACT	IVE II	VGRE tadecy	DIEN 1 amm	T: nonium	r chlor	ide	
4403 III(CITIALIOI	al bivu., suite bios, holeros	s, UA 30093	i.	May 14, 1997									Ì		
DATA	DATA REQUIREMENTS		SOURCE	E OF DATA SATISFYING REQUIREMENT	ISFYING REQ	UIREMENT				MRID EPA / OR O IDEN	ACCE THE	MRID NUMBER EPA ACCESSION NUMBI OR OTHER EPA IDENTIFYING NUMBER		MRID NUMBER EPA ACCESSION NUMBER, OR OTHER EPA IDENTIFYING NUMBER	•
Regulation Part 158/ Guideline Number	Name of Test	Submitted by Applicant	Date Submitted	Submitted by another person/firm (name)	Permission letter enclosed	Public literature	N.A. or waiver or other (explain)								
61-1	Product Identity and Disclosure of Ingredients	×	05/14/97					4	4	2	7	6	4	0	
61-2	Description of Beginning Materials and Manufacturing Process	×	05/14/97					4	4	2	7	6	4	0	2
61-3	Discussion of Formation of Impurities	×	05/14/97					4	4	2	7	6	4	0	Э.
62-1	Preliminary Analysis	×	08/15/97					4	4	3	5	_	6	0	_
62-2	Certification of Ingredient Limits	×	08/15/97					4	4	6	2	-	6	0	_
62-3	Analytical Method for Enforcement of Limits	×	08/15/97					4	4	8	5	1	6	0	1
63-2	Color	×	05/14/97					4	4	2	7	6	4	0	4
63-3	Physical State	x	05/14/97					4	4	2	7	6	4	0	4
63-4	Odor	x	05/14/97					4	4	2	7	6	4	0	4
63-7	Density, Bulk Density, or Specific Gravity	×	05/14/97		:			4	4	2	7	6	4	0	4
5 ⁻						i									

2	

PRODUCT NAME: BioShield AM 500 I	ME: 00 I		EPA REG	EPA REG. NO. OR FILE SYMBOL: 70871-E	SYMBOL:		FORMULATOR EXEMPTION ASSERTED: Yes	OR EXE	EMPTIC	N ASS	ERTE			
APPLICANT'S NAME ANI BioShield Technologies, Inc. 4405 International Blvd., Sui	APPLICANT'S NAME AND ADDRESS: BioShield Technologies, Inc. 4405 International Blvd., Suite B109, Norcross, GA 30093	, GA 30093	API	APPLICATION DATE: May 14, 1997	VTE:	3-(tri	NAME OF ACTIVE INGREDIENT: 3-(trimethoxysilyl) propyldimethyloctadecyl armonium chloride	F ACTI	VE INC hylocta	REDII decyl ar	ENT: mmoniu	n chlo	ride	
DATA	DATA REQUIREMENTS		SOURCE	SOURCE OF DATA SATISFYING REQUIREMENT	ISFYING REQ	UIREMENT				RID NI PA AC(R OTH	MRID NUMBER EPA ACCESSION NUMBER, OR OTHER EPA IDENTIFYING NUMBER	N NG	MBER	-5
Regulation Part 158/ Guideline Number	Name of Test	Submitted by Applicant	Date Submitted	Submitted by another person/firm (name)	Permission letter enclosed	Public literature	N.A. or waiver or other (explain)							
63-5, -6, -8, - 9, -10, -11, - 13, -14, -15, - 16, -19, -20, - 21	Melting Point, Boiling Point, Solubility, Vapor Pressure, Dissociation Constant, Octanol/Water Partition Coefficient, Stability, Oxidizing or Reducing Action, Flammability, Explodability, Miscibility, Corrosion Characteristics, Dielectric Breakdown Voltage						n/a							
63-12	hd	x	05/14/97					4	4 2	7	6	4	0	4
63-17	Storage Stability						being conducted							
63-18	Viscosity	X	05/14/97					4	4 2	7	6	4	0	4
81-1 81-2 81-3 81-5 81-5	Oral LDso - Rat Dermal LDso - Rabbit Inhalation LCso - Rat Primary Dermal Irritation - Rabbit Dermal Sensitization -	× ••••	05/14/97				Waiver*							
	H								1				1	

PRODUCT NAME: BioShield AM 500 I	ME: 600 I		EPA REG.	EPA REG. NO. OR FILE SYMBOL: 70871-E	SYMBOL:		FORMULATOR EXEMPTION ASSERTED: Yes	R EXE	EMPTIC Yes	NO AS	SERT	ED:		1
APPLICANT'S NAME AND BioShield Technologies, Inc.	APPLICANT'S NAME AND ADDRESS: BioShield Technologies, Inc.		APF	APPLICATION DATE:	VTE:	3-(tr)	NAME OF ACTIVE INGREDIENT: 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride	ACTIV	TE INC	REDI decyl a	ENT:	ium ch	loride	
4405 Internation	4405 International Blvd., Suite B109, Norcross, GA 30093	. GA 30093		May 14, 1997										
DATA	DATA REQUIREMENTS		SOURCE	CE OF DATA SATISFYING REQUIREMENT	ISFYING REQ	UIREMENT				MRID NUMBER EPA ACCESSION NUMBER, OR OTHER EPA IDENTIFYING NUMBER	TUMB CESS IER E	ER ION N PA	UMBI	Ж,
Regulation Part 158/ Guideline Number	Name of Test	Submitted by Applicant	Date Submitted	Submitted by another person/firm (name)	Permission letter enclosed	Public literature	N.A. or waiver or other (explain)	•						
81-4	Primary Eye Irritation - Rabbit						to be submitted by June 30, 1998							
91-2 (b)	Hard Surface - Disinfectant (general/broad spectrum efficacy)		04/05/74	Dow Coming**				0 0	1	9	4	6	0	6
91-2 (e)	Hard Surface - Fungicidal (pathogenic fungi		04/05/74	Dow Coming**				0 0	1	9	4	6	0	6
91-2 (i)	Hard Surface - Additional Organisms		04/05/74	Dow Coming**				0 0	1	9	4	6	0	6
91-2 (j)	Hard Surface - Sanitizing (for non-food contact surfaces)		04/05/74	Dow Coming				0 0	1	9	4	6	0	6
91-2 (m)	Residual Self-Sanitizing on Hard Surfaces	•	04/05/74	Dow Coming**				0 0	1	9	4	6	0	6
91-4 (a)(2)	Disinfecting Laundry Additives		04/05/74	Dow Corning**	:			0 0	1	9	4	6	0	6
91-4 (a)(3)	Sanitizing Laurdry Additives		04/05/74	Dow Coming**				0 0	1	9	4	6	0	6
253 1 4 (a)(4)	Self-Sahitizing Laundry Additives		04/05/74	Dow Corning**				0 0	1	9	4	6	0	6

							,	
		ۍ ا		6	6	6	6	6
	ride	MRID NUMBER EPA ACCESSION NUMBER, OR OTHER EPA IDENTIFYING NUMBER		0	0	0	0	0
ä	m chlo	N NU		6	6	6	6	6
RTE	NT: moniu	MRID NUMBER EPA ACCESSION NUMBI OR OTHER EPA IDENTIFYING NUMBER		4	4	4	4	4
ASSE	EDIE:	ACC OTHE		9	9	9	9	9
TION	INGR	MR EPA OR		1	1	-	-	1
XEMI Yes	TIVE			0	0	0	0	0
OR E	OF AC			0	0	0	0	0
FORMULATOR EXEMPTION ASSERTED: Yes	NAME OF ACTIVE INGREDIENT: 3-(trimethoxysilyl) propyldimethyloctadecyl armonium chloride		N.A. or waiver or other (explain)					
	3-(tri	UIREMENT	Public literature					ļ
SYMBOL:	TE:	ISFYING REQ	Permission letter enclosed					
EPA REG. NO. OR FILE SYMBOL: 70871-E	APPLICATION DATE: May 14, 1997	SOURCE OF DATA SATISFYING REQUIREMENT	Submitted by another person/firm (name)	Dow Corning"	Dow Coming**	Dow Coming**	Dow Coming**	Dow Corning"
EPA REG.	APF	SOURCE	Date Submitted	04/05/74	04/05/74	04/05/74	04/05/74	04/05/74
	, GA 30093		Submitted by Applicant					
ME: 00 I	APPLICANT'S NAME AND ADDRESS: BioShield Technologies, Inc. 4405 International Blvd., Suite B109, Norcross, GA 30093	DATA REQUIREMENTS	Name of Test	Carpet Sanitizers	Mattresses and Upholstery Sanitizers	Impregnated Self- Sanitizing Fabrics/Textiles	Toilet Bowl and Urinal Surfaces (Disinfectant)	Toilet Bowl and Urinal Surfaces (Sanitizer)
PRODUCT NAME: BioShield AM 500 I	APPLICANT'S NAME AND BioShield Technologies, Inc. 4405 International Blvd., Sui	DATA	Regulation Part 158/ Guideline Number	91-4 (b)	91-4 (c)	91-4 (d)	91-7 (a)(1)	91-7 (a)(2)

*Acute Toxicology waiver request found acceptable for Guideline Numbers (81-2, -2, -3, -5, and -6); see EPA toxicology review dated September 2, 1997. *Data now owned by Aegis Environmental Management Inc.





Reviewer ID

Submission No. 532438

Data Package No. D240666

CODING FORM FOR APPLICATI	CONS FOR RE	GISTRATIO	N/AMENTHENTS		
File Symbol/Reg. No.	0871-	E = 3	Act	ion Code /	87
10 Descriptor (Amend/Re	enoisi c us:	only)			
Intrastate Call-in	/_/ (Y)	Yes 15	Child-resist	ant /_/(C) Certification
	(N)	.No	Packaging	<u>/</u> /(s) Service Person
$ \overline{20} $ Registration Type:				<u>//</u> (.R) Non-residentia
(1) Conditiona	· /	(2) Unco	nditional	/ / /	Use Only
25 Proposed Classifica	tion: 1 <u>30</u> 1	Final Cla	ssification:	<u>/_</u> / (N) Not-Applicable
/ (R) Restricted	<u> </u>	(R) Restr	icted	· ·	
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Efficacy

Jellinek, Schwartz & Connolly, Inc.

1525 Wilson Boulevard, Suite 600 Arlington, VA 22209 (703) 527-1670 • Fax: (703) 527-5477



Hand Delivered

Consultants in Environmental Science, Policy & Management

October 15, 1997

Ms. Velma Noble (Acting PM 31)
Regulatory Management Branch I
Antimicrobials Division (7510W)
Office of Pesticide Programs
U. S. Environmental Protection Agency
Document Processing Desk
Room 266A, Crystal Mall 2
Arlington, VA 22202

Re: Response to EPA's September 5, 1997, and October 10, 1997, Letters BioShield AM 500 and AM 500 I (EPA File Symbols 70871-R and -E)

Dear Ms. Noble:

Thank you for your letters dated September 5, 1997, and October 10, 1997, regarding the registration applications for BioShield AM 500 and AM 500 I (EPA File Symbols 70871-R and -E, respectively). On behalf of BioShield Technologies, Inc. (BioShield; 4405 International Boulevard, Suite B109, Norcross, Georgia, 30093; EPA Company Number 70871), we are responding to your letters, and submitting materials in support of BioShield's registration applications.

Acute Toxicology

We understand from EPA's September 2, 1997, acute toxicology review that the acute toxicology waiver requests for BioShield AM 500 and AM 500 I were acceptable for all acute toxicology studies except the primary eye irritation study (Guideline Number 81-4). EPA believes that the proposed precautionary language on the draft product labels significantly overstates the risk of the product; thus, EPA is requesting that a primary eye irritation study be submitted prior to registration of these two products.

Since the overstatement of the risk of the BioShield AM 500 and AM 500 I products will not increase any hazards to human health, but rather ensures that the proposed product is used with caution, we propose that EPA grant conditional registrations of BioShield AM 500 and AM 500 I. Such registrations would be based on the condition that BioShield conduct a primary eye irritation study. BioShield proposes to submit the results of this study to EPA by June 30, 1998, and, at that time, request appropriate, revised precautionary language for these products.

Efficacy Data Requirements

We understand from your September 5, 1997, letter that BioShield needs to clarify the efficacy claims on the AM 500 and AM 500 I product labels in order to determine what efficacy data will be required for registration of the products. We believe the information in this letter along with the following items will address these concerns:

- an application form (EPA Form 8570-1);
- five copies of the revised product label;
- one copy of the revised product label with the revisions highlighted;
- a Certification with Respect to Citation of Data form (EPA Form 8570-29);
- a data matrix; and
- a letter from Aegis Environmental Management Inc. (Aegis) regarding MRID Number 164909.

In order to clarify the efficacy claims and target pests for the AM 500 and AM 500 I products, the following section was added to the draft product labels and collateral labeling under the "Approved Uses" heading:

"Target Pests: The active ingredient in AM 500 I is effective against gram positive and gram negative bacteria, fungi (including mold and mildew), algae, and yeasts. The following species have been tested: Salmonella choleraesius, Staphylococcus aureas, Pseudomonas aeruginosa, Streptococcus faecalis, Eschericia coli, Asperillus niger, and Trichophyton interdigitale."

In addition, the following label revisions were made to the draft product labels and collecteral labeling.

• The statement "..and air treatment products" was added to the first paragraph under the Approved Uses heading.

- The statement "AM 500 [I] can be used for incorporation into and treatment of the
 following items or substrates to impart durable, broad-spectrum, antimicrobial
 protection:" replaced the statement "AM 500 [I] can be used to impart durable,
 broad-spectrum, antimicrobial protection to substrates for the following
 applications:" in order to clarify the uses of the product.
- The following uses were added to the list in the Approved Uses section of the labels and collateral labeling: building materials; concrete and materials used to make concrete; fibers, such as polypropylene fibers and fabrics made from those fibers; fibers, such as polypropylene fibers and fabrics made from those fibers for incorporation into concrete, and pool and spa filters.

We understand that additional data may be required to support BioShield's efficacy claims and the specific target pests. Thus, we are citing MRID number 164909, a study titled "Physical and Chemical Properties [of Dow Corning X9-5700]," in support of the use sites and claims listed on the BioShield AM 500 and AM 500 I product labels. Although this study is titled "Physical and Chemical Properties" and is coded as such when located in the National Pesticide Information Retrieval System, it also includes several efficacy studies for Dow Corning products and product dilutions containing the same active ingredient as the AM 500 and AM 500 I products (please see the enclosed letter from Aegis). We understand that this study was reviewed and accepted by EPA.

Product Chemistry

BioShield submitted Series 62 product chemistry data to the Agency on August 15, 1997 (MRID # 44351901). These data included the Preliminary Analysis (Guideline Number 62-1), the Certification of Ingredient Limits (Guideline Number 62-2), and an Analytical Method for Enforcement of Limits (Guideline Number 62-3) (MRID Number 44351901). Please note that storage stability studies (Guideline Number 63-17) for AM 500 and AM 500 I, including the formulations containing the alternate were initiated on June 27, 1997, at Springborn Laboratories, Inc., in Wareham, Massachusetts. We will submit these data as soon as they become available.

As you requested in your October 10, 1997, letter, attached please find a revised Confidential Statement of Formula (CSF) for AM 500 (EPA File Symbol 70871-R) that lists all of the ingredients in the product. I understand that Kimberly Lowe of Jellinek, Schwartz & Connolly, Inc., discussed the requested revisions with Barbara Pringle of your office. This revised CSF provides a complete chemical identity of the proposed product.

Inert ingredient information may be entitled to confidential treatment

If you have any questions about this application, please contact me at (703) 312-8531 or Kimberly Lowe at (703) 312-8539.

Sincerely,

Blane Dahl

Registration Manager

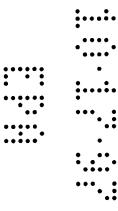
Jellinek, Schwartz & Connolly, Inc.

Authorized Representative of

BioShield Technologies, Inc.

Enclosures

c: Joachim Berkner, BioShield Technologies, Inc.



े केच उँ International Boulevard, Suite B109 Norcross, GA 30093

BioShield AM 500 I

ANTI-MICROBIAL AGENT & PROTECTANT

A Silicone Quaternary Ammonium Salt (For Manufacturing Use Only)

92.0% 100.0% 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride..... Active Ingredient: Inert Ingredients:

KEEP OUT OF REACH OF CHILDREN DANGER

Lot No. EPA Reg. No. xxxx-xx

EPA EST. xxxxx-GA-xx

NET CONTENTS: 8 oz., 1 gal., 5 gal., or 55 gal.

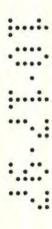
STATEMENT OF PRACTICAL TREATMENT

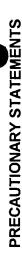
IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.

person. Drink promptly a large quantity of milk, eggwhites, gelatin solution, or, if these are not available, drink large quantities of IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious water. Avoid alcohol.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.





HAZARDS TO HUMANS AND DOMESTIC ANIMALS

and protective eyewear (goggles and face shield). Wash thoroughly with soap and water after handling and before eating, drinking, inhaled. Harmful if inhaled. Avoid contact with skin, eyes, or clothing. Avoid breathing vapor. Wear protective clothing and gloves, Corrosive. Causes irreversible eye damage. May be fatal if swallowed. Causes skin imtation. Harmful if absorbed through skin or using tobacco, or using the toilet. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in

De-activation of AM 500 I can be achieved by the addition of anionic surfactant in quantity equivalent to that of AM 500 I.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

SEE COLLATERAL LABEL FOR COMPLETE USE DIRECTIONS

Do not use in conjunction with NOTE: This product should not be used or compounded with any bleach or oxidizing agents. anionic surfactants.

For formulating use into end-use products listed in the attached "Information About Antimicrobial Agents" pamphlet.

APPROVED USES ..

AM 500 I is approved for use in formulating disinfectants, sanitizers and microbiocides for use in laundry additives, carpet treatment products, upholstery and drapery treatment products, building cleaning and treatment products.

Target Pests: The active ingredient in AM 500 Lis effective against gram positive and gram negative bacteria, fungi (including mold and mildew), algae, and yeasts. The following species have been tested: Salmonella choleraesius, Staphylococcus aureas, Pseudomonas aeruginosa, Streptococcus faecalis, Eschericla coli, Asperillus niger, and Trichophyton interdigitale.

APPROVED USES (cont.)

AM 500 I can be used for incorporation into and treatment of the following items or substrates to impart durable, broad-spectrum, antimicrobial protection:

- Air filters for fumaces, air-conditioners, air purification devices, automobiles, recirculating air handling systems;
 - Air filters/materials;
- Aquarium filter material;
- Bed sheets, blankets, and bedspreads;
- Buffer pads (abrasive and polishing);
 - Building materials;
- Carpets and draperies;
- Concrete and materials used to make concrete;
- Fibers, such as polypropylene fibers, and fabrics made from those fibers;
- Fibers, such as polypropylene fibers, and fabrics made from those fibers used for incorporation into concrete;
- Fiberfill for upholstery, sleeping bags, apparel, etc., where the fiber is cotton, natural down, nylon, polyester, rayon, or wool;
 - Fiberglass ductboard;
- Fire hose fabric;
- Humidifier belts:
- Mattress pads and ticking;
- Men's underwear and outerwear;
- Non-woven disposable diapers;
- Non-woven polyester;
 - Outerwear apparel;
- Disposable polyurethane foam cushions for Lapidus Airfloat Systems;
- Polyurethane foam for household, industrial, and institutional sponges and mops;
 - Polyurethane and polyethylene foam, when covered;
- Polyurethane foam for packaging and cushioning in non-food contact applications;
 - Polyurethane foam used as a growth medium for non-food crops and plants;
 - Pool and spa filters;
- Pre-moistened towelettes and tissue wipes (these do not impart pesticidal properties)
- Roofing materials defined as shingles, roofing granules, wood shakes, felt, stone and synthetic overcoats;
 - Sand bags, tents, tarpaulins, sails, and ropes;
 - Athleticand casual shoes;
- Shoe insoles;
- Shower ourtains:
- wool/acrylic/pylgn/Lycra; provides residual self-sanitizing activity against athlete's foot fungus (Trichophyton mentagrophytes) on the sock, Jugable for up to 10 repeated washings; prevents 99.9 percent of the growth of athlete's foot fungus on the sock; Socks comprised of nylon, nylon/orlon, cotton/nylon, linen/Lycra, acrylic/polypropylene/nylon/Lycra, wool/silk/nylon/Lycra and
 - Theow ruge;
- Toweling made of 100 percent cotton, 100 percent polyester, and blends of the two fibers;
 - Toilet tank and seat covers;

- Upholstery made of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polyolefins, polypropylene, rayon, spandex, vinyl, and wool
- Vacuum cleaner bags and filters;
- Vinyl paper-wallpaper for non-food contact surfaces;
- Disposable wiping cloths that can be used for multiple purposes such as dusting or washing furniture, cars, walls, windows, floors, appliances, dishes, counter tops, etc.; the wiping cloths do not impart pesticide properties;
 - Women's hosiery; and
- Women's intimate apparel.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

inaccessible to children and away from food or feed. AM 500 I has a minimum shelf life of 12 months from the date of shipment Pesticide Storage: Store in original, tightly closed containers below 30°C (86°F) and above 0°C (32°F) in a secure area from BioShield.

violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance. Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

FOR MORE INFORMATION CONCERNING THIS PRODUCT, PLEASE CONSULT THE MATERIAL SAFETY DATA SHEET (MSDS). THE MSDS CAN BE OBTAINED BY WRITING BIOSHIELD TECHNOLOGIES, INC. AT 4405 INTERNATIONAL BOULEVARD, SUITE B109, NORCROSS, GEORGIA, 30093.

COLLATERAL LABELING

BioShield Technologies, Inc.

4405 International Boulevard, Suite B109 Norcross, GA 30093

Information About Antimicrobial Agents

AM 500 I — FOR MA	NUFACTURING USE ONLY
	er
	Silicone quaternary ammonium salt
Physical Form	Low-viscosity liquid
Special Properties	Surface bondability
Primary Uses	As an active ingredient for formulating disinfectants, sanitizers and microbiocides for use in laundry additives, carpet treatment products, upholstery and drapery treatment products, and building cleaning and
	treatment products, and building cleaning and treatment products to give a surface-durable antimicrobial treatment effective and active against a wide variety of bacteria, fungi, algae and yeasts

	CH₃
Structure	 [(CH₃O)₃Si(CH₂)₃N–C ₁₈ H₃ ₇] ⁺ CI
	 CH₃
Concentration	5.0%
Appearance	Colorless liquid
Solubility	Miscible in all proportions Wiffi
Thermal Stability °C (°F)	water, ethanol, and methanol. Stable to 30°C (86°F)
Specification Writers: Please contact BioShie	eld for information regarding specifications
	••••
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DESCRIPTION

AM 500 I is BioShield's designation for 3-(trimethoxysilyI) propyloctadecyldimethyl ammonium chloride containing 5 percent active ingredient by weight. Alkoxysilanes of this nature have been shown to form durable bonded coatings to a number of materials (see "References" section).

AM 500 I offers users the following features:

- Good durability—BIOSHIELD AM 500 I Antimicrobial Agent imparts durable, broad-spectrum, biostatic activity to the surface of a wide variety of substrates; it is leach-resistant and nonmigrating and is not consumed by microorganisms.
- Broad-spectrum activity—effective against gram positive and gram negative bacteria, fungi, algae and yeasts; antimicrobial action is exhibited on contact.
- Increased efficiency—through proper application, durable bacteriostatic, fungistatic and algistatic surfaces can be attained with a minimum amount of AM 500 I.

BENEFITS

The following benefits are derived when a formulation containing the active ingredient is applied to a surface:

- Provides hygienic freshness and combats deterioration caused by bacteria, fungi, algae, and yeasts.
- Inhibits growth of bacteria and mildew on the treated article.
- Prolongs the life of a article by inhibiting the growth of bacteria and mildew.
- Provides a durable, residual, antimicrobial treatment that is not destroyed by repeated cleaning.
- Resists development of bacterial and fungal odors.
- · Retains freshness by resisting the growth of odor-causing bacteria and mildew (fungus).
- Provides a chemical treatment that enables fabrics to resist odors.
- Provides a unique chemical treatment that resists mildew and bacteria growth and imparts odor resistance.
- Contains no phenols, tin, heavy metals, lead, mercury, or formaldehyde.
- Product performance with little degradation up to 375°F.

Materials treated with formulations containing the antimicrobial agent AM 500 I are preserved by the bacteriostatic, fungistatic and algistatic action imparted by the active ingredient. AM 500 I inhibits the growth of microorganisms that are responsible for causing odor, discoloration and deterioration. It also provides residual inhibition of microorganisms to aid in the control of these deleterious effects. AM 500 I forms a coating on a wide variety of substrates and antimicrobial action is exhibited on contact.

APPROVED USES

AM 500 I is approved for use in formulating disinfectants, sanitizers and microbiocides for use in laundry additives, carpet treatment products, upholstery and drapery treatment products, building cleaning and treatment products, and air treatment products.

<u>Target Pests:</u> The active ingredient in AM 500 I is effective against gram positive and gram negative bacteria, fungi (including mold and mildew), algae, and yeasts. The following species have been tested: Salmonella choleraesius, Staphylococcus aureas, Pseudomonas aeruginosa, Streptococcus faecalis, Eschericia coli, Asperillus niger, and Trichophyton interdigitale.

AM 500 I can be used for incorporation into and treatment of the following items or substrates to impart durable, broad-spectrum, antimicrobial protection:

- Air filters for furnaces, air-conditioners, air purification devices, automobiles, recirculating air handling systems;
- Air filters/materials;
- Aguarium filter material;
- Bed sheets, blankets, and bedspreads;
- Buffer pads (abrasive and polishing);
- Building materials;
- · Carpets and draperies;
- Concrete and materials used to make concrete;
- Fibers, such as polypropylene fibers, and fabrics made from those fibers;
- Fibers, such as polypropylene fibers, and fabrics made from those fibers used for incorporation into concrete;
- Fiberfill for upholstery, sleeping bags, apparel, etc., where the fiber is cotton, natural down, nylon, polyester, rayon, or wool;
- Fiberglass ductboard;
- Fire hose fabric;
- Humidifier belts:
- Mattress pads and ticking:
- Men's underwear and outerwear;
- Non-woven disposable diapers;
- Non-woven polyester;
- Outerwear apparel;
- Disposable polyurethane foam cushions for Lapidus Airfloat Systems;
- Polyurethane foam for household, industrial, and institutional sponges and mops;
- Polyurethane and polyethylene foam, when covered;
- Polyurethane foam for packaging and cushioning in non-food contact applications;
- Polyurethane foam used as a growth medium for non-food crops and plants;
- Pool and spa filters:
- Pre-moistened towelettes and tissue wipes (these do not impart pesticidal properties);
- Roofing materials defined as shingles, roofing granules, wood shakes, felt, stone and synthetic.
 overcoats;
- Sand bags, tents, tarpaulins, sails, and ropes;
- Athletic and casual shoes;
- Shoe insoles;
- Shower curtains;
- Socks comprised of nylon, nylon/orlon, cotton/nylon, linen/Lycra, acrylic/polypropylone/nylon/Lycra, wool/silk/nylon/Lycra and wool/acrylic/nylon/Lycra; provides residual self-sanitizing activity against athlete's foot fungus (*Trichophyton mentagrophytes*) on the sock, durable for up-to-10 repeated washings; prevents 99.9 percent of the growth of athlete's foot fungus on the sock;
- Throw rugs;
- Toweling made of 100 percent cotton, 100 percent polyester, and blends of the two fibers;
- Toilet tank and seat covers;
- Umbrellas;

- Upholstery made of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polyolefins, polypropylene, rayon, spandex, vinyl, and wool;
- Vacuum cleaner bags and filters;
- Vinyl paper-wallpaper for non-food contact surfaces:
- Disposable wiping cloths that can be used for multiple purposes such as dusting or washing furniture, cars, walls, windows, floors, appliances, dishes, counter tops, etc.; the wiping cloths do not impart pesticide properties;
- Women's hosiery; and
- Women's intimate apparel.

DIRECTIONS FOR USE

AM 500 I can be incorporated directly into formulations used to make the end products listed in this bulletin.

AM 500 I can also be diluted with water or other solvents (for example, alcohol, and ketones) and then applied to organic or inorganic substrates by brushing, dipping, padding, soaking, spraying, fogging or by using foam finishing techniques to give a final treatment of 0.1 to 1.0 percent by weight active ingredient.

After applying the antimicrobial agent, the substrate can then be dried at temperatures from ambient to a maximum of 160° C (320° F) to effect complete condensation of silanol groups and to remove water, solvents and/or traces of methanol from hydrolysis. Optimum application and drying conditions, such as time and temperature, should be determined for each application before use.

EPA REGISTRATION REQUIREMENTS

The applications for which this product are used require approval by the Environmental Protection Agency on an end-use basis in regard to claims made thereof. Formulators are responsible for satisfying registration requirements for their products.

PRECAUTIONARY STATEMENTS

Corrosive. Causes irreversible eye damage. May be fatal if swallowed. Causes skin irritation. Harmful if absorbed through skin or inhaled. Harmful if inhaled. Avoid contact with skin, eyes, or clothing. Avoid breathing vapor. Wear protective clothing and gloves, and protective eyewear (goggles and face shield). Wash thoroughly with soap and water after handling and before eating, drinking, using tobacco, or using the toilet. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark; this product might be toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

AM 500 I, by standard biological oxygen demand (BOD) and total oxygen demand (TOD) determination, does not appear to be biodegradable. Potential harm to the environment is minimized, however, because of the minimal amount of chemical applied and its durable coupling to surfaces.

Inactivation of solutions containing AM 500 I may be accomplished by one of the following methods:

- addition of an anionic surfactant or detergent in quantity equivalent to that of AM 500 I in softitions or
- addition of Triton X-100 nonionic detergent at a final concentration of 10,000 ppm (1.0 percent volume/volume) or greater to bath solutions up to 1.0 percent volume/volume of AM 500 I.

Every effort should be made to contain accidental spills of AM 500 I to the immediate area. This may be accomplished by the use of sandbags to confine the spill to facilitate cleanup and disposal. Contaminated sand may then be disposed of by burial in an approved landfill. Many spills may be cleaned up with rags by wiping and/or mopping and allowing the liquid to absorb into the fabric. The rags may then be disposed of by incineration.

Floor drains in areas of material use should be protected with sandbags to contain accidental spills.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in original, unopened containers below 3°C (86°F) and above 0°C (32°F). AM 500 I has a minimum shelf life of 12 months from the date of shipment from BioShield.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Before handling, read product label in its entirety

IMPORTANT: WARRANTY AND DISCLAIMER INFORMATION

BioShield Technologies, Inc., warrants that the product conforms to its chemical description and is reasonably fit for the purposes stated in this bulletin when used in accordance with directions under normal conditions of use; but this warranty of fitness for a particular purpose does not extend to the use of this product contrary to bulletin instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to seller, and buyer assumes the risk of any such use.

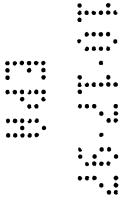
BIOSHIELD SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING THE WARRANTY OF MERCHANTABILITY.

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BioShield Technologies, Inc. 4405 International Boulevard, Suite B109 Norcross, GA 30093



Jellinek, Schwartz & Connolly, Inc.

1525 Wilson Boulevard, Suite 600 Arlington, VA 22209 (703) 527-1670 • Fax: (703) 527-5477



Hand Delivered

Consultants in Environmental Science, Policy & Management

443519-00

August 15, 1997

Ms. Velma Noble (Acting PM 31)
Regulatory Management Branch I
Antimicrobials Division (7510W)
Office of Pesticide Programs
U. S. Environmental Protection Agency
Document Processing Desk
Room 266A, Crystal Mall 2
Arlington, VA 22202

Re: BioShield AM 500 and BioShield AM 500 I (EPA File Symbols 70871-R and -E) Response to EPA's letter dated August 12, 1997

Dear Ms. Noble:

Thank you for your letter of August 12, 1997, regarding registration applications for the BioShield AM 500 and AM 500 I products (EPA File Symbols 70871-R and -E, respectively). On behalf of BioShield Technologies, Inc. (BioShield; 4405 International Boulevard, Suite B109, Norcross, Georgia, 30093), this letter is in response to the issues raised in your letter.

Product Chemistry

We agree that the BioShield AM 500 end product will not be registered until the AM 500 I manufacturing use product is registered.

Confidential Statements of Formula

We are enclosing two copies of revised CSFs for AM 500 I and AM 500, one copy with the changes highlighted. The following revision was made to the AM 500 I CSF per your letter:

the single CSF for AM 500 I now lists
 and the CSFs for alternate formulations
 dated May 14, 1997, are hereby withdrawn.

MEMBERS OF THE JSC GROUP OF COMPANIES

Jellinek, Schwartz & Connolly, Inc. • Arlington, VA 22209 USA • (703) 527-1670 • Fax (703) 527-5477

JSC International Ltd. • Harrogate, North Yorkshire HG1 5QY • UK • (1423) 520245 • Fax (1423) 520297

Sielken, Inc. • Bryan, TX 77802 USA • (409) 846-5175 • Fax (409) 846-2671

JSC, Spensley • Denver, CO 80202 USA • (303) 623-3100 • Fax (303) 623-3130

Additional revisions made to both CSFs are as follows:

- the producer of the products has been changed (Box 2); and
- the lower certified limit for the active ingredient (Box 14b) has been lowered slightly per the results from the five batch preliminary analysis.

Series 62 Product Chemistry

Enclosed are data for Pesticide Assessment Guideline Series 62 to fulfill the requirements for the two proposed products. A single study is being submitted to fulfill data requirements for both BioShield AM 500 and AM 500 I because the two proposed products are identical in composition. Enclosed are three copies of the following study report:

44351901 • Preliminary Analysis, Certification of Ingredient Limits, and Analytical Method for Enforcement of Limits for BioShield AM 500 and BioShield AM 500 I.

Series 63 Product Chemistry

Springborn Laboratories, Inc., is currently conducting storage stability studies (EPA Guideline Number 63-17) on BioShield AM 500 and AM 500 I and the formulations containing the alternate. We will submit this study as soon as it is available. According to PR Notice 92-6, we understand submission of this study is not required prior to product registration because 1) no efficacy data should be required for the proposed use patterns, 2) we do not anticipate that the results of the storage stability will indicate that the concentration of active ingredient falls outside of the certified limits or that degradates of toxicological concern will be present, and 3) product instability is not suspected.

Labeling

Attached please find six copies of revised labels for the AM 500 and AM 500 I products, one copy with the revisions highlighted. We have revised the labels as follows per your letter:

- the statement "See Collateral Label for complete use directions" was added to the Directions for use section of the main label;
- all approved uses listed on the Collateral Label are now listed on the main label as well;
- the net contents statement has been placed on the front panel; and
- the brochure is now titled "Collateral Labeling."

Acute Toxicology

All acute toxicology data requirements for BioShield AM 500 and AM 500 I, including the Acute Primary Eye Irritation (Guideline Number 81-4) data requirement, were addressed in the original May 14, 1997, submission. That submission included a request for a waiver of

further testing for AM 500 and AM 500 I (see Volumes VII and VIII). In the waiver requests, justification is provided for the Acute Primary Eye Irritation requirement based on BioShield's restrictive precautionary language on its label (category I toxicity), including a Danger signal word. Any additional data that could be submitted would not result in more restrictive precautionary labeling since the highest possible risk from the use of the product is assumed. In addition, we cited the study titled "Acute Toxicologic Properties of Dow Corning Q9-5700: Laboratory Project ID: AD-0003" (MRID# 40385201). According to EPA's Reregistration Status Report Card for Trimethoxysilyl propyl dimethyl octadecyl ammonium chloride (copy attached for your convenience), this study was acceptable to satisfy the Acute Primary Eye Irritation Data Requirement. Thus, based on the proposed precautionary labeling and the Dow Corning study cited in the previously submitted waiver request, we believe BioShield has satisfied the Acute Primary Eye Irritation data requirement.

The data required for registration of BioShield AM 500 and AM 500 I (with the exception of the storage stability study) are now complete, and we understand that there are no other issues regarding registration of these products. Thus, we look forward to the timely registration of these products.

If you have any questions, please give me a call at (703) 312-8531.

Sincerely,

Blane Dahl

Registration Manager

Jellinek, Schwartz & Connolly, Inc.

Authorized Representative of BioShield Technologies, Inc.

Enclosures

c: Joachim Berkner, BioShield Technologies, Inc.



Bioshield Technologies, Inc. 4405 International Blvd., Ste. B109 Norcross, GA 30093

ATTN: Kimberley Lowe, Agent

SUBJECT: BIOSHIELD AM 500

EPA File Symbol 70871-R BIOSHIELD AM 500 I

EPA File Symbol 70871-E

Dear Ms. Lowe:

This letter is a follow-up to the fax review of the acute toxicity waiver request, I sent you. As you can see the Agency needs a primary eye irritation study (Guideline No. 81-4) on the formulated product, Bioshield AM 500, EPA File Symbol 70871-R.

Further review of your file on Bioshield AM 500 shows that you will need to clarify the efficacy studies. The product booklet states the product is for "disinfectants, sanitizers and micorbiocides uses...". What type of organisms are you controlling? Are they human pathogens or odor-causing bacteria, fungi, algae and yeasts? You must submit efficacy studies or waiver requests from doing the efficacy or MRID's of previous studies already done. List the human pathogens on the label. Odor-causing organiams do not require efficacy studies.

Please submit product chemistry data for preliminary analysis, analytical methods and the storage stability for the MUP, so all chemical analyses for these products will be complete.

-					-		
			CONCURRENC	ES			
SYMBOL	15/0W						
SURNAME							
DATE	949						
EPA Form	n 1320-1A (1/90)		Printed on Paracles	I Danes		OFFICI	SHE COPY

If you have any further questions, please contact Ms. Barbara Pringle at (703) 308-6236.

Sincerely,

Velma Noble
Acting Product Manager 31
Regulatory Management Branch I
Antimicrobial Division (7510W)

TX REPORT ***********

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United States Environmental Protection Agency Washington, D.C. 20460

Office of Prevention, Pasticides & Toxic Substances Office of Pesticide Programs

Antimicrobials Division

Fax Number (703) 308-8481

FACSIMILE REQUEST/COVER SHEET

(Please type of print clearly in black ink only)	
SEND FAX TO: Nemo: Kimberley Lone	
April 1	-
EAX Phone No: 703-57-5477	
Office Phone No: 703-312-8539	
FROM: Banharas Pingle	
Division/Branch:	
Office Phone No. 703 - 308-6236	
Office Room No:	
Mell Code: 2570W Date: 9-4-99 Time:	
Number of Pages (with this cover sheet):	~.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

9/2/97

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Subject:

BioShield AM 500 I, EPA File Symbol 70871-E

Data Package D236250

BioShield AM 500, EPA File Symbol 70871-R

Data Package D236249

From:

Wallace Powell, Biologist Risk Assessment and Science Support Branch

Antimicrobials Division (7510W)

Thru:

Laura E. Morris, Acting Team Leader West Williams Risk Assessment and Science Support Branch 09.

Antimicrobials Division (7510W)

mp Care 09/03/9+ Norman Cook, Chief

Risk Assessment and Science Support Branch

Antimicrobials Division (7510W)

To:

Velma Noble, Product Manager, Team 31 Barbara Pringle, Team Reviewer, Team 31

Registration Branch I Antimicrobials Division

BACKGROUND

The applicant, BioShield Technologies, Inc. (as represented by Jellinek, Schwartz & Connolly, Inc.), for registration of the two subject products has submitted a request for waivers of all product acute toxicity testing. These two products are identical in composition - BioShield AM 500 (EPA File Symbol 70871-R) is a 100% repackaging of BioShield AM 500 I (EPA File Symbol 70871-E).

BioShield AM 500 I uses a

CONTAINS CONFIDENTIAL BUSINESS INFORMATION

Manufacturing process information may be entitled to confidential treatment

Product ingredient source information may be entitled to confidential treatment



The applicant has cited several acute toxicity studies, submitted for the Dow Corning material during the years 1987 through 1994, claiming that EPA accepted these studies when it registered the Dow Corning product. (The studies with MRID Numbers 001285-46 through -49 appear to be the ones on which initial registration was based; the studies cited now by the applicant may or may not include re-submissions of those older studies.)

No Reregistration Eligibility Decision (RED) document has yet been issued for the active ingredient in these products, which is assigned to Reregistration Case 3148, Trimethoxysilyl Quats.

RECOMMENDATION

With the exception of the statements reflecting eye irritation hazard in the "Hazards to Humans and Domestic Animals" paragraph, the BioShield AM 500 I and BioShield AM 500 label statements would appear acceptable if based on the Reg. No.

In terms of current labeling guidelines, the precautionary statements are not entirely consistent with the acute toxicity categories which were assigned to its source material, Reg. No.

at the time of the source material's registration. However, it is recommended that this issue be attended to at the time of reregistration of the trimethoxysilyl quats, and that the precautionary statements proposed for the two BioShield products be accepted with the exception of the eye irritation human hazard statements mentioned above.

It is recommended that a primary eye irritation study (guidelines no. 81-4) be required for the BioShield material.

It is not clear that the BioShield material should be in Category I for eye irritation (note that the Material Safety Data Sheet for BioShield AM 500 I mentions that the material caused "slight" irritation in rabbits). No Toxicity Category for eye irritation can be assigned to these products since they represent a significant dilution of the material. To reflect the source material's Category I rating for eye irritation in the BioShield products may result in a significant overstatement of the hazard. It is recommended that the eye irritation study be required in the absence of any further information from the applicant.

Product ingredient source information may be entitled to confidential treatment*

DZ36250

AUG 1 2 1997

Bioshield Technologies, Inc. 4405 International Blvd., Ste. B109 Norcross, GA 30093

ATTN: Blane Dahl, Agent

SUBJECT: BIOSHIELD AM 500

EPA File Symbol 70871-R BIOSHIELD AM 500 I EPA File Symbol 70871-E

Applications Dated May 14, 1997

Dear Mr. Dahl:

A review of the above named applications show the following defiencies:

PRODUCT CHEMISTRY

Bioshield AM 500--This product may not be registered until Bioshield AM 500 I, is registered. Confidential Statement of Formula (CSF) dated May 14, 1997 will be accepted when EPA File Symbol 70871-E is registered. Product chemistry data for EPA File Symbol 70871-E will satisfy product chemistry data for this product.

Bioshield AM 500I--Alternate formulations for manufacturing use products are not acceptable. Manufacturing use products may have alternate sources of supply for the inert ingredients. Since the only change in each product is a different then all may be as alternate only one CSF is needed. Please submit a revised CSF and list all as alternate sources.

Please submit data for preliminary analysis, analytical methods and the storage stability so that all chemical analyses will be complete for this MUP.

LABELING--For the end-use product, Bioshield AM 500, place all uses directions on the label or a statement such as "See Collateral Label for complete use directions.". All the "Approved Uses" must be placed on the label. Place the Net

	Contents'	statemer	nt on the	TONOGRAPA	Pel. The	brochure	must be	
SYMBOL	7510W							
SURNAME	Punile							
DATE	8-12-97							
	A						oreici.	MARK E CORV

EPA Form 1320-1A (1/90)

labeled as "Collateral Labeling" which can placed on the label or the MUP and end-use products.

<u>Acute Primary Eye Irritation</u>--Please provide study and or justification for a waiver from data for this the primary eye irritation. This formulation is not the same as the Dow Corning 5772, this is a 5% formulation rather than a 72.1% formulation.

If you have any further questions, please contact Ms. Barbara Pringle at (703) 308-6236.

Sincerely,

Velma Noble

Acting Product Manager 31 Regulatory Management Branch I Antimicrobial Division (7510W)

			Reviewer ID		ngle
			Submission N	No. <u>ح</u>	24425
			Data Package	e No.	
			2000 11000		
CODING FORM FOR APPLICAT	IONS FOR RE	GISTRATIC	N/AMENDMENTS		
File Symbol/Reg. No. 7	0871-E	- PM 3	Actio	on Code /	86
10 Descriptor (Amend/R	esubmisions	only)	Apply For Ne	w Kegist	rotion
Intrastate Call-in		1	Child-resistar Packaging		Certification
	(N)	No			Service Person
20 Registration Type:				/_/ (R	Non-residential Use Only
(1) Conditiona	1	(2) Unco	onditional	/ · / (N	Not-Applicable
25 Proposed Classifica	tion: <u>30</u>	Final Cla	assification:		, not applicable
(R) Restricte	d	(R) Restr	ricted		
// (G) General		(N) Not (Classified		
35 Date on Applicati	on: 104 8	PA Recei	ved Date:	40 Date Rec	eived by PM
013-11491 MO DAY Y	7 0 R	13 / MD D	19 917 AY YR	015 0	21 / 91 7 DAY YR
80 Method of Support	::				
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// (4) Not Applicabl	le // (7) Total	Submission	F14	
// (5) Not Submitted		8) Select	ive Method		
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75-DAY RESPONSE DUE DAT	E: /_/(Y)	Yes	/_/(N) NO		

BioShield Technologies, Inc.

4405 International Boulevard, Suite B109 Norcross, GA 30093

BioShield AM 500 I

ANTI-MICROBIAL AGENT & PROTECTANT A Silicone Quaternary Ammonium Salt

(For Manufacturing Use Only)

3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride..... Active Ingredient: Inert Ingredients:

2.0%

KEEP OUT OF REACH OF CHILDREN DANGER

EPA Reg. No. xxxx-xx

EPA EST. xxxxx-GA-xx

STATEMENT OF PRACTICAL TREATMENT

FINHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical | Set medical attention. | Set medical attenti

person. Drink promptly a large quantity of milk, eggwhites, gelatin solution, or, if these are not available, drink large quantities of affention.

IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious water. Avoid alcohol.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

and protective eyewear (goggles and face shield). Wash thoroughly with soap and water after handling and before eating, drinking inhaled. Harmful if inhaled. Avoid contact with skin, eyes, or clothing. Avoid breathing vapor. Wear protective clothing and gloves, Corrosive. Causes irreversible eye damage. May be fatal if swallowed. Causes skin irritation. Harmful if absorbed through skin or using tobacco, or using the toilet. Remove contamínated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in

De-activation of AM 500 I can be achieved by the addition of anionic surfactant in quantity equivalent to that of AM 500 I.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

NOTE: This product should not be used or compounded with any bleach or oxidizing agents. Do not use in conjunction with anionic surfactants.

For formulating use into end-use products listed in the attached "Information About Antimicrobial Agents" pamphlet.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal

inaccessible to children and away from food or feed. AM 500 I has a minimum shelf life of 12 months from the date of shipment Pesticide Storage: Store in original, tightly closed containers below 30°C (86°F) and above 0°C (32°F) in a secure area from BioShield.

violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

FOR MORE INFORMATION CONCERNING THIS PRODUCT, PLEASE CONSULT THE MATERIAL SAFETY DATA SHEET (MSDS). THE MSDS CAN BE OBTAINED BY WRITING BIOSHIELD TECHNOLOGIES, INC. AT 4405 INTERNATIONAL BOULEVARD, SUITE B109, NORCROSS, GEORGIA, 30093.

Bio-Shield AM 500 I

Material Safety Data Sheet

Date Prepared: January 4, 1996

24 Emergency Telephone: (800) 424-9300

BioShield Customer Service: (404) 848-7784

N/E - Not Established N/A - Not Available

Product Identification

Labeled Name: Bio-Shield AM 5001 Trade Name or Synonym: Bio-Shield Chemical Name: Trade Secret **Chemical Family: Mixture**

Hazardous Ingredients

PPM

Physical and Chemical Characteristics	(Fire and Explosion	n Data)
---------------------------------------	---------------------	---------

212°F/100°C Water Boiling Point (760 MM HG)..... 1.00 Specify Gravity (At 770E6/25 DE6 C)..... Vapor Pressure (At 77°F/25°C)..... 100MM Percent Volatile by Volume..... .0083 Above 1 Vapor Density (Air = 1)..... Evaporation Rate (Ether = 1)..... N/E

Greater Than 90 Solubility in Water.....

Reactivity in Water.....

Appearance and Odor..... Pale yellow, no odor 167.5°C - closed cup Flash Point.....

Flammable Limits in Air (% by Volume)..... Lower N/A Upper N/A

Not Applicable Extinguisher Media.....

Auto-Ignition Temperature..... NE Unusual Fire and Explosion Hazards..... None

NFPA HAZARD: Health 1 Flammability	0	Reactivity	0
------------------------------------	---	------------	---

Physical Hazards:

Stability..... Stable

Conditions to Avoid..... Exposure to water or air until ready to use Incompatible Materials..... Oxidizing material can cause a reaction

Hazardous Decomposition Products..... Nitrogen oxides, carbon monoxide when burning

Hazardous Polymerization..... Will not occur

Conditions to Avoid..... N/A

Health Hazards: N/E - Not Established N/A - Not Available Threshold Limit Value..... N/E **Toxicological Data:** 1. Acute Oral Toxicity..... LD₅₀ (Rats) 12.27 g/kg Low Toxicity -(Concentrate) LD₅₀ (Rabbits) 7.95 g/kg MUP Level (Concentrate) Dermal Toxicity..... LD₅₀ (Rats) 81.9 g/L MUP Level (Concentrate) Inhalation Toxicity..... Eye Irritation..... (Rabbits) caused slight eye irritation (Rabbits) slight erythema and edema Skin Irritation.....

Listed as Carcinogen or Potential Carcinogen by:

1.	National Toxicology Program	No
2.	LA.R.C. Program	No
3.	OSHA	No

Emergency First Aid Procedures

Inhalation - No Special Requirements

Skin/Eyes - Wipe off and flush with water for 15 minutes. Get medical attention if ill effects occur.

Ingestion - If Ill Effects Occur Get medical attention. Do not induce vomiting.

Special Protection Information

Respiratory Protection	None normally required
	None normally required
Ventilation	None normally required
Gloves	Impervious/Rubber
Eye Protection	Safety goggles or face shield

Special Precautions and Spill/Leak Protection

Steps to be taken if material is released or spilled: Do not contaminate water, food, or feed by material.

Water Disposal Methods: Dispose according to Federal RCRA and applicable state and local regulations.

Transportation: D.O.T. Emergency Guide No. 31

PRODUCT CHEMISTRY REVIEW - Antimicrobial Division SUBJECT:

> Reg. No. or File Symbol 70871-E DP. Barcode 1236247

Manufacturing-Use [/] OR End-Use Product []

TO:

31 Walks Francis
PM Team No. __ Barbara Pringle

Anna Skapars, Chemist FROM:

Risk Assessment and Science Support Branch

THRU: Norman Cook, Chief

Risk Assessment and Science Support Branch

SUMMARY OF INFORMATION REVIEWED AND FINDINGS

This application is for registration of new manufacturing use product. Submitted are three Confidential Statements of Formula one basic and two alternate Formulations.

Registrant should not that for manufacturing use products alternate formulations are not acceptable. Manufacturing use products may have alternate sources of supply for must ingredients. Since the only change in each product is different than all and all may be as alternated. only one Confidential Formula.

Registrant should submit revised Confidential Statement of Formule and list all

In block 7 enter the founds per gallon or bulk density

Provided product chemistry date in MRID Nos 442794-01, 442794-02, 442794-03 and 442794-04 provides date for Secideline Series 61, 62 and 63. This date is in compliance with 40 CFR fait 158:155-158.190 and it satisfies product chemistry data requirement except for Buideline Ref No. V62-1-pulliminary analysis

62-2 - certification of the ingreduct limits 62-3 - analytical methods to verify entified limits 63-17- Stange and Stability date

Thise date will be submitted where complete. 287 | Cinna Skapas

PRODUCT CHEMISTRY REVIEW

END-USE PRODUCT [] MANUFACTURING-USE PRODUCT [] EPA Reg. No. (or File Symbol No.) 70871- E

		ion [v]	Reregistration [] Case No.:			
DP Barcode/Chemist: Anna Skapans						
1)		3)	-			
2)		4)				
1.	Produ	ct Name: Bio Shield AM 500 I				
2.	Company:					
3.	Type "ME Exp	of Submission: New [v] Resubmission -TOO" [] Alternate Formulation t Use Permit [] Other (Specify)	[] Amendment [] [] REPACK []			
4.	CONFI	DENTIAL STATEMENT OF FORMULA				
	4a.	Type of formulation and source regis	tration			
		 Non-integrated formulation system Are all TGAIs used registered 	• yes [v] • no []			
		Integrated formulation system	[]			
		 If "ME-TOO", specify EPA Reg. No. oproduct: 	of existing			
	4b.	Clearance of inerts for non-food or Cleared for food use under 40CFR§180 • yes [] • no []. If yes: • c[Cleared for non-food use: • yes	.1001:			
	4c.	Physical state of product: VISCoul	liquid			
	4d.	The chemical IDs, analytical information that for the TGAIs), density, pH, and consistent with that given in GRN 61 63-12, and 63-15, respectively.	d flammability are , 62, and 63-7,			

4e.	Density (or bulk density for solids): at 'C.0.9997 g/n
4f.	pH (if dissolved or dispersed in water): 4.8 (5 part/100 (w/w)
4g.	Flash point and/or flame extension: N/A
4h.	NCs and CLs are acceptable: \cdot [$$] \cdot not acceptable []
4i.	Active ingredient(s) NC_ LCL UCL
	A. 3-(trimithoxysilyl) propyl dimithyl B. Octadecyl ammonium chloride. 5.0% 4.75% 5.25%
	c.
	D
4j.	For products produced by an integrated formulation system:
	 All impurities of toxicological significance have an UCL: • yes [] • no [] • not applicable [V]
	 All impurities ≥ 0.1% in the product have been identified: yes [] · no [] · not applicable [/]
PRODU	CT LABEL
5a.	The active ingredients statement (chemical IDs and NCs) is consistent with the CSF: • yes [/] • no []
5b.	The formulation contains one of the following: 10% or more of a petroleum distillate: 1% or more of methyl alcohol: sodium nitrite at any level: a toxic List 1 inert at any level: yes [] no [/] arsenic in any form: yes [] no [/]
5c.	If yes to any of the above, does the inert ingredients statement contains a footnote indicating this? • yes [] • no [] • not applicable [/]
5 d .	The appropriate warning statement regarding flammability or explosive characteristics of the product are given on the label: • yes [/] • no [] • not applicable []

5.

- 5e. The storage and disposal instructions for the pesticide and container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses: yes [√] no []
- 6f. Does the product require an expiration date at which time the NC falls below the LCL (based on the one year storage stability data or other information):

 yes []

 no [$\sqrt{ }$]

6. PRODUCT CHEMISTRY (GRN 61, 62, 63)

6a. Chemical IDs/Manufacture/Analytical Information	Accept of Information	MRID No.
61-1 Chemical ID (see Appendix)	A	442794-02
61-2a Manufacturing Process ²	A	442794-02
61-2b Formulation Method ³	A	442794-0
61-3 Discussion of Impurities4	A	442794-03
62-1 Analysis ⁵	will be ted	
62-2 Certified Limits ⁶	A	CSF
62-3 Analytical Method for AIs ⁷	will be submit	ly

PRODUCT NAME: BioShield AM 500 I	ME:		EPA REG.	EPA REG. NO. OR FILE SYMBOL: 7 087(-ら	SYMBOL:		FORMULATOR EXEMPTION ASSERTED: Yes	R EXEMP	TION A	SSERTED:	291
APPLICANT'S	APPLICANT'S NAME AND ADDRESS:		APP	APPLICATION DATE:	TE:	3 (;-:	NAME OF	NAME OF ACTIVE INGREDIENT:	INGRED	IENT:	
4405 International Blvd., Sui	4405 International Blvd., Suite B109, Norcross, GA 30093	GA 30093		May 14, 1997		3-(111	э-(пшешохузнут) рторуташтетутоскачесут апплощин стогие	утанцентут	octadecy	апплонши	TOTIGE
DATA	DATA REQUIREMENTS		SOURCE (SOURCE OF DATA SATISFYING REQUIREMENT	ISFYING REQ	UIREMENT			MRID	MRID NUMBER	IMRED
									OR OT	OR OTHER EPA IDENTIFYING NUMBER	1BER
Regulation Part 158/ Guideline Number	Name of Test	Submitted by Applicant	Date Submitted	Submitted by another person/firm (name)	Permission letter enclosed	Public literature	N.A. or waiver or other (explain)				
63-11	Octanol/Water Partition Coefficient						n/a				
63-12	pH	×	05/14/97								
63-13	Stability						n/a				
63-14	Oxidizing or Reducing Action						n/a				
63-15	Flarmability						n/a				
63-16	Explodability						n/a				
63-17	Storage Stability						being conducted				
63-18	Viscosity	×	05/14/97								
63-19	Miscibility						n/a				
63-20	Corrosion Characteristics			:			n/a				
63-21	Dielectric Breakdown Voltage						n/a				
81-1	Oral LD ₅₀ - Rat	×	05/14/97				Waiver				
81-2	Dermal LD _∞ -Rabbit	×	05/14/97				Waiver				
81-3	Inhalation LCs - Rat	×	05/14/97				Waiver				

PRODUCT NAME: BioShield AM 500 I	ME:		EPA REG.	EPA REG. NO. OR FILE SYMBOL: $70871-6$	SYMBOL:		FORMULATO	FORMULATOR EXEMPTION ASSERTED:
APPLICANT'S NAME AND BioShield Technologies, Inc.	APPLICANT'S NAME AND ADDRESS: BioShield Technologies, Inc.		APP	APPLICATION DATE:	TE:	3-(tri	NAME OF	NAME OF ACTIVE INGREDIENT: 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride
4405 Internation	4405 International Blvd., Suite B109, Norcross, GA 30093	, GA 30093		May 14, 1997	i	,	money (stays) prop	
DATA	DATA REQUIREMENTS		SOURCE	SOURCE OF DATA SATISFYING REQUIREM	SFYING REQ	UIREMENT		MRID NUMBER EPA ACCESSION NUMBER, OR OTHER EPA IDENTIFYING NUMBER
Regulation Part 158/ Guideline Number	Name of Test	Submitted by Applicant	Date Submitted	Submitted by another person/firm (name)	Permission letter enclosed	Public literature	N.A. or waiver or other (explain)	
81-4	Primary Eye Irritation -	×	05/14/97				Waiver	
	Rabbit					1		
81-5	Primary Dermal Irritation -	×	05/14/97	 			Waiver	
	Rabbit							
81-6	Dermal Sensitization -	×	05/14/97				Waiver	
	Guinea Pig							

\$EPA

United States

Environmental Protection Agency Washington, DC 20460

Form Approved OMB No. 2070-0060 Approval Expires 05-31-95

	Certification with Re	spect to Citation of Data	
Applicants Name and Add	dress	EPA File Symbol/Registration Number	or 70871-E
	hnologies, Inc. cional Boulevard, Suite B109	Product Name BioShield AM	
Norcross, GA		Date of Application 5/14/199	97
for the same us Form 8570-27) 1. This applicated, the product that submitted if uses under	your product is a 100% repackaging of anotes, you do not need to submit this form. You ation is supported by all data submitted or chis application is supported by all data in the is identical or substantially similar and the this application sought the initial registration data requirements in effect on the date of 3, or 4 below that pertain to your application.	cited in the application. In addition, ne Agency's files that concern the proat is one of the types of data that wou ion of a product of identical or similar of approval of this application. (Che	if cite-all options are perties or effects of this ald be required to be ar composition and intended
2. I certify tha	t, for each study cited in support of this app	olication for registration that is an ex	clusive use study.
I ai	n the original submitter*; or		
I I h	ave obtained the written permission of the c	original submitter for	, which is
			ert name of chemical)
	(insert names of companies) th the appropriate chemical name) to cite the		inginal data submitters
3. I certify tha	t, for each study cited in support of this app	olication for registration that is not an	exclusive use study;
a. X I am	the original data submitter*; or		
7.7	ve obtained the written permission of the or	riginal data submitter for	, which is
wit	(for multiple c (insert names of companies) h the appropriate chemical name) to cite th	hemicals link the companies who are	me of chemical) c original data submitters
b. I ha	ve notified in writing the companies	for	that
thos Rod com	(insert cases) (inser	s application and have offered to: (a)) and 3(c)(2)(D) of the Federal Insec negotiations to determine which data	ticide, Fungicide and are subject to the
Com	panies for		r multiple
listed meth Com	(insert names of companies) nicals link the companies who are original on the Pesticide Data Submitters List for a od or cite-all option under Selective Methodonies for for (insert names of companies) icals link the companies who are original of nave submitted the studies which I have cite	all active ingredients contained in my d*). (Also, sign the General Offer S (fo (insert name of chemical) data submitters with the appropriate of	r multiple
obtain	tify that for each study cited in support of t written permission because all time periods atrix identifying these studies is attached.	s for exclusive use and data compens. (Note: a Data Matrix is not required	ation have expired. under the cite-all method)
Signature BLE W	Name and Title Blane Da	ahl, Jellinek, Schwartz & y, Inc., Auth. Rep. of	Date 5/14/97
		lagred to paymonipersationsto other persons, wi	
Signature	Name and Title		Date -

Paperwork Reduction Act Notice

The public reporting burden for this collection of information is estimated to average 2.5 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining needed data, and completing and reviewing this application form. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: Chief, Information Policy Branch, 2136, U.S. Environmental Protection Agency, 401 M Street, S. W., Washington, DC 20460; and to Office of Management and Budget, Paperwork Reduction Project (2070-0055), Washington, DC 20503, marked "Attention Desk Officer for EPA."

\$EPA

United States

Environmental Protection Agency Washington, DC 20460

Form Approved OMB No. 2070-0060 Approval Expires 05-31-95

Certification with Respect to Citation of Data		
Applicants Name and Address	EPA File Symbol/Registration Number 17 0 271-E	
BioShield Technologies, Inc.		
4405 International Boulevard, Buite B109 Norcross, GA 30093	BIOSHIEIG AM 300 1	
Holeloss, GA 30073	Date of Application 5/14/1997	
product that is identical or substantially similar and that is submitted if this application sought the initial registration uses under the data requirements in effect on the date of a items 2 and 3, or 4 below that pertain to your application. 2. I certify that, for each study cited in support of this application. I am the original submitter*; or I have obtained the written permission of the original formultiple chemical name) to cite that submitter that, for each study cited in support of this application. I certify that, for each study cited in support of this application. I am the original data submitter*; or I have obtained the written permission of the original data submitter.	and in the application. In addition, if cite-all options are Agency's files that concern the properties or effects of this is one of the types of data that would be required to be no fa product of identical or similar composition and intended approval of this application. (Check the appropriate boxes, in eation for registration that is an exclusive use study. Similar submitter for, which is	
with the appropriate chemical name) to cite that	study*; or	
have submitted data I have cited to support this at those data in accordance with section 3(c)(1)(F) a Rodenticide Act (FIFRA); and (b) Commence neg compensation requirement of FIFRA and the amount have notified are: Companies for	companies) (insert name of chemical) pplication and have offered to: (a) Pay compensation for and 3(c)(2)(D) of the Federal Insecticide, Fungicide and gotiations to determine which data are subject to the bunt and terms of compensation due, if any. The companies (for multiple (insert name of chemical) ta submitters with the appropriate chemical name) active ingredients contained in my product (cite-all). (Also, sign the General Offer Statement below.) (insert name of chemical) a submitters with the appropriate chemical name)	
Rippo Hon	Inc., Auth. Rep. of Date 5/14/97	
General Offer to Pay: I hereby offer and ag the approval of this application, to the extent r	ree to pay compensation to other persons, with regard to	
Signature Name and Title	Date -	



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PRODUCT NAME:				DAT	DATA REQUIREMENT LISTING	EMENT LI	STING						7
APPLICANT'S NAME AND ADDRESS:	PRODUCT NAI BioShield AM 5	ME:		EPA REG.	NO. OR FILE	SYMBOL:		FORMULATO	R EXEMPTION Yes	N ASSE	RTED:		-2 9
DATA REQUIREMENTS	APPLICANT'S BioShield Techn 4405 Internation	NAME AND ADDRESS: ologies, Inc. al Blvd., Suite B109, Norcross	, GA 30093	APF	LICATION DA May 14, 1997	TE:	3-(tri	NAME OF	ACTIVE INGR	REDIEN ecyl arm	VT: monium chl	loride	
Halation 1888 Name of Test Permission Public Permission Permission Product Identity and Disclosure of Ingredicatis Applicant Product Identity and Disclosure of Ingredicatis Applicant Permission of Permission	DATA	REQUIREMENTS		SOURCE	OF DATA SATI	SFYING REQ	UIREMENT		MR EP. OR IDE	A ACCI OTHE	MBER ESSION N R EPA ING NUM	UMBER,	
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Description of Beginning Materials and Manufacturing Process	61-1	Product Identity and Disclosure of Ingredients	X	05/14/97									
Discussion of Formation of Impurities x 05/14/97 decided <	61-2	Description of Beginning Materials and Manufacturing Process	X	05/14/97									
Color x 05/14/97	61-3	Discussion of Formation of Impurities	X	05/14/97							.6.	BEC	.,
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Boiling Point x 05/14/97 05/14/97 05/14/97 05/14/97 05/14/97 05/14/97 05/14/97 05/14/97 05/14/97 </td <td>63-6</td> <td>Melting Point</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td>n/a</td> <td></td> <td></td> <td>3: 7 d</td> <td>340/</td> <td><u></u></td>	63-6	Melting Point						n/a			3: 7 d	340/	<u></u>
Solubility Vapor Pressure Dissociation Constant	63-7	Boiling Point Density, Bulk Density, or Specific Gravity	×	05/14/97				n/a			. 59	10	
Vapor Pressure Dissociation Constant	63-8	Solubility						п/а					
Dissociation Constant	63-9	Vapor Pressure						n/a					
	63-10	Dissociation Constant						n/a					

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United States

Environmental Protection Agency

Washington, DC 20460

F	ormulator's Exempti	on Statement	
Applicant's Name and Address		EPA File Symbol/Registration Number 70 871-E	
BioShield Technologies, In 4405 International Blvd., S Norcross, GA 30093		Product Name BioShield AM 5001	
	e 1.30 anyliki jo ar jer simil	Date of Confidential Statement of Formula IEPA Form 857 5/14/97	10-4)
As an authorized representative of the	applicant for registration of	the product identified above, I certify that:	1
(1) This product contains the follow	ring active ingredient(s):		-34
3(trimethoxysilyl) propy	ldimethyloctadecyl amm	onium chloride	
ingredient in the manufacturing,	formulation or repackaging a Section 3, is purchased by	esent solely as the result of the use of that active another product which contains that active ingred us from another producer, and is labeled for at lea	
(3) Indicate by checking (A) or (B) b	elow which paragraph applic	es:	
attached to this statement. That name, the source of the active in	formula statement indicates ingredient(s) listed in paragra OR of Formula (CSF) (EPA Form	8570-4) referenced above and on file with the EP	
(4) The following active ingredients			
• The following deate ingredients	Source	io formulativo exemptorii	
Active Ingredient	Product Name	e Registration Number	ATH
3(trimethoxysily1) propyldimethyloctadecy1 ammonium chloride *Product ingredient source into	formation may be entitled	97 MV 19 P2:55	
Froduct Ingredient Source Ini		1 to confidential treatment	
Signature / 1 Do 0	Name and Title Blane D	Dahl, Date	

EPA Form 8570-27 (Rev. 8-95)

Authorized Representative of BioShield Technologies, Inc.

Jellinek, Schwartz & Connolly,

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5/14/97

Inc.

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Chief, Information Policy Branch, PM-223 U.S. Environmental Protection Agency 401 M Streeet, S.W. Washington, DC 20460

and to

Office of Management and Budget
Paperwork Reduction Project (2070-0060)
Washington, DC 20503



SEPA

United States

Environmental Protection Agency

Washington, DC 20460

Formulator's Exemption Statement (40 CFR 152.85)

Applicant's Name and Address

BioShield Technologies, Inc. 4405 International Blvd., Suite B109 Norcross, GA 30093 EPA File Symbol/Registration Number

10871-6

Product Name

BioShield AM 5001

Date of Confidential Statement of Formula (EPA Form 8570-4) 5/14/97

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

3(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride

- Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.
- (3) Indicate by checking (A) or (B) below which paragraph applies:
- (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).
 - (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.
- (4) The following active ingredients in this product qualify for the formulator's exemption.

	Source	
Active Ingredient	Product Name	Registration Number
3(trimethoxysily1) propyldimethyloctadecyl n ammonium chloride		97 MY 19 P2 55
Product ingredient so	urce information may be entitled to c	onfidential treatment
Signature Lo Dal	Name and Title Blane Dahl,	Date 5/14/97

EPA Form 8570-27 (Rev. 8-95)

BioShield Technologies, Inc.

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Chief, Information Policy Branch, PM-223 U.S. Environmental Protection Agency 401 M Streeet, S.W. Washington, DC 20460

and to

Office of Management and Budget Paperwork Reduction Project (2070-0060) Washington, DC 20503

U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs

BIOSHIELD TECHNOLOGIES, INC. 4405 INTERNATIONAL BLVD. SUITE B109 NORCROSS, GA 30093

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 05/19/97. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

May 20, 1997

BIOSHIELD TECHNOLOGIES, INC C/O JELLINEK, SCHWARTZ & CONNOLLY, INC 1525 WILSON BLVD - STE 600 ARL, VA 22209

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

ATTN: BLANE DAHL

PRODUCT NAME: BIOSHIELD AM 500 I

COMPANY NAME: BIOSHIELD TECHNOLOGIES, INC

OPP IDENTIFICATION NUMBER: 250768
EPA FILE SYMBOL: 70871-E
EPA RECEIPT DATE: 05/19/97

SUBJECT: RECEIPT OF APPLICATION FOR A NEW REGISTRATION

DEAR REGISTRANT

The Office of Pesticide Programs has received your application for a new registration, and it has passed an administrative screen for completeness.

Please note that this is only a notification of receipt of your application. This is only the first step in the application process, and does NOT constitute approval.

If you have any questions, please contact Marshall Swindell, Acting Product Manager 31 at (703) 308-6341.

Sincerely,

Front End Processing Staff Information Services Branch

Program Management and Support Division

KECD EPA/OPP/OPD

Jellinek, Schwartz & Connolly, Inc.

1525 Wilson Boulevard, Suite 600 Arlington, VA 22209 (703) 527-1670 • Fax: (703) 527-5477



Consultants in Environmental Science, Policy & Management

Hand Delivered

442794-00

May 14, 1997

Ms. Rebecca Cool (Acting PM 31)
Regulatory Management Branch I
Antimicrobials Division (H7505W)
Office of Pesticide Programs
U. S. Environmental Protection Agency
2800 Crystal Drive
Arlington, VA 22202

Re:

AM 500 I and AM 500

Application for Pesticide Registration

Dear Ms. Cool:

On behalf of BioShield Technologies, Inc. (BioShield, 4405 International Boulevard, Suite B109, Norcross, Georgia, 30093), we are submitting an application for pesticide registration for the manufacturing use product, AM 500 I (containing the active ingredient 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride, CAS# 27668-52-0) and an application for an end use product, AM 500, which is identical in composition to the subject MUP. Thus, the product chemistry data included in this submission are provided once (but the required three copies of these data are enclosed).

This is BioShield's first pesticide application. Please assign an EPA Company Number for BioShield

Because BioShield purchases the active ingredient from a registered source and is claiming a formulator's exemption, no data on 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride technical grade active ingredient (TGAI) are included in this submission.

9

This application package is formatted in accordance with PR Notice 86-5 and contains the following required information to support the registration of AM 500 I and AM 500:

VOLUME#	TITLE
I Administrative	Transmittal Document (this letter); Application for Registration (EPA Form 8570-1);
Material AM 500 I	Confidential Statements of Formula for the basic and alternate formulations (CSF) (EPA Form 8570-4); Certification with Respect to Citation of Data (EPA Form 8570-29);
(Manufacturing Use Product)	Data Matrix; Formulator's Exemption Statement (EPA Form 8570-27); Material Safety Data Sheet; Proposed Draft Labeling (5 copies).
	(1 copy), and Authorization Letter from BioShield authorizing Jellinek, Schwartz &
	Connolly, Inc., to act on their behalf regarding registration matters.

II Administrative	Application for Registration (EPA Form 8570-1); Confidential Statement of Formula (CSF) (EPA Form 8570- Certification with Respect to Citation of Data (EPA Form 8570-1).	4); 570-29):
Material AM 500	Data Matrix; Formulator's Exemption Statement (EPA Form 8570-27);	97
End Use Product)	Material Safety Data Sheet; and	要
	Proposed Draft Labeling (5 copies).	MNY 19 P2 55
hree conies of the	following data and information are being submitted:	Ρ2
mee copies of the	following data and information are being submitted.	Ċ

VOLUME#	GUIDELINE #	MRID	TITLE
III	61-1	44279401	Product Identity and Composition of AM 500 I and AM 500
IV	61-2	44279402	Description of Beginning Materials and the Manufacturing Process of AM 500 I and AM 500
V	61-3	44279403	Discussion of Formation of Impurities in AM 500 I and AM 500
VI	63-2, 63-3, 63-4, 63-7, 63-12, 63-18	44279404	AM 500 I and AM 500 Product Chemistry Studies (Color, Physical State, Odor, Density, pH, Viscosity)
VII	Series 81	Admin	Waiver Request of Requirement for Further Testing for AM 500 I
VIII	Series 81	Admin	Waiver Request of Requirement for Further Testing for AM 500

There are three Confidential Statements of Formula (CSFs) submitted for the AM 500 I manufacturing use product (one "basic" formula and two "alternative" formulations). BioShield believes that the Product Chemistry data (Series 63) conducted on the formulation stated on the "Basic" CSF also apply to the alternate formulations (except storage stability and viscosity) because the basic and alternate formulations are

please see the CSFs and Volume IV, "Description of the Beginning Materials and the Manufacturing Process of AM 500 l and AM 500"). These formulations are expected to have the same physical properties (color, physical state, odor, density, and pH).

Data for preliminary analysis (EPA Guideline Number 62-1) and the analytical method (EPA Guideline Number 62-3) will be submitted shortly to fulfill these data requirements for AM 500 I and AM 500. At the same time, the ingredient limits for each of the ingredients will be certified (EPA Guideline Number 62-2), and this information will be submitted.

In addition, a storage stability study (EPA Guideline Number 63-17) is being conducted on the basic and alternate formulations for AM 500 I and will be submitted when it is complete.

If you have any questions about this application, please feel free to contact me at (703) 312-8531.

Sincerely,

Blane Dahl

Registration Manager

Jellinek, Schwartz & Connolly, Inc.

Authorized Representative of BioShield Technologies, Inc.

Enclosures

c: Joachim Berkner, BioShield Technologies, Inc.

*Manufacturing process information may be entitled to confidential treatment

Product ingredient source information may be entitled to confidential treatment

WAIVER REQUEST OF REQUIREMENT FOR FURTHER TESTING AM 500

May 14, 1997

Test Type and Guideline Reference Number:

Acute Oral Toxicity	Guideline #81-1
Acute Dermal Toxicity	Guideline #81-2
Acute Inhalation Toxicity	Guideline #81-3
Primary Eye Irritation	Guideline #81-4
Primary Dermal Irritation	Guideline #81-5
Dermal Sensitization	Guideline #81-6

Test Substance: AM 500

BioShield Technologies, Inc.'s (BioShield) AM 500 is an end-use product containing 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride, a silicone quaternary ammonium salt as the active ingredient

AM 500 will be used as an all purpose cleaner and kitchen cleaner, a disinfectant spray, a tub and tile mold and mildew cleaner, a carpet and upholstery cleaner, a toilet bowl cleaner, a laundry additive, and as other products outlined on the proposed product label in Volume II of this submission.

All of the above-mentioned studies have been conducted on DOW Corning 5772. This waiver request pertains to the studies to be conducted solely with AM 500.

Summary

5772.

A waiver request for the above six acute toxicity studies on AM 500 is requested based on existing toxicology data on DOW CORNING 5772.

However, BioShield is intending to retair. the existing precautionary statements and the signal word based on the toxicity categories dictated by acute toxicology studies conducted with DOW CORNING

Basis for Waiver Request:

Existing Data

Acute toxicity studies on DOW CORNING 5772 exist in various animal species. The studies described below represent some of the critical studies conducted with this active ingredient. These studies have been accepted by EPA when it registered DOW CORNING 5772. BioShield has been granted permission by Aegis Environmental Management Inc. to reference these data when writing this Acute Toxicity data waiver. No additional new information on acute toxicity would be generated by conducting these studies again. The following is list of studies that BioShield is referencing:

- MRID 40385201 Hobbs, E. (1973) Acute Toxicologic Properties of Dow Corning Q9-5700: Laboratory Project ID: AD-0003. Unpublished compilation prepared by Dow Corning Corp.
- MRID 42456511, Devries, C.; Siddiqui, W. (1983) Acute Oral Toxicity of DOW CORNING 5772 Antimicrobial Agent: Project X9-6346. Prepared by DOW CORNING CORP.
- MRID 43219901, Devries, C.; Siddiqui, W. (1983) Acute Dermal Toxicity of DOW CORNING X9-6346 (DOW CORNING 5772 Antimicrobial Agent): Lab Project Number 4211-3. Unpublished study prepared by DOW CORNING CORP.
- MRID 41157803, Kolesar, G., Siddiqui, W., Staton, E. (1985) An Acute Aerosol Inhalation Toxicity Study with Dow Corning 5772 compound in Rats: Report No. 1312. Unpublished study prepared by Sow Corning Corp.
- MRID 93218047, Dwane, M. (1990) Dow Corning Corp. An acute Dermal Irritation Study of Dow Corning 5772 Antimicrobial Agent: Project X9-6346. Prepared by DOW CORNING CORP.
- MRID 42456513 Devries, C.; Siddiqui, W. (1983) Phase 3 New Submission:
 Acute Dermal Irritation Study of Dow Corning 5700 Antimicrobial
 Agent: Lab Project Number: X9-6346. Unpublished study prepared by
 Dow Corning corp.
- MRID 42197401 Hoffman, R. (1992) A Skin Sensitization Study of Dow corning 5700 Hydrolysate in Guinea Pigs: Lab Project Number: 1992-10000-36929. Unpublished study prepared by Dow Corning Corp.

Exposure Potential From Intended Uses

BioShield believes that because the product is the exposure hazards are not high. The product label's strong precautionary language will discourage any use of this product not in accordance with the directions for use. In additon, the product label also outlines the appropriate protective clothing to be used and precautions to be taken during use of AM 500.

Summary

Acute toxicity data of DOW CORNING 5772 on all above-mentioned studies (acute oral toxicity, Guideline #81-1; acute dermal toxicity, Guideline #81-2; acute inhalation toxicity, Guideline #81-3; primary eye irritation, Guideline #81-4; primary dermal irritation, Guideline #81-5; and dermal sensitization, Guideline #81-6) are available at the Agency. In addition, BioShield and Dow Corning have reached an agreement to share these data; therefore, BioShield believes that these studies should satisfy the acute toxicity data requirement for its product. BioShield believes that conducting additional studies is not going to provide new information on toxicity of its product. Therefore, available data on DOW CORNING 5772 at the Agency justifies a waiver of additional acute toxicity studies.

structions on reverse before completing form Form Approved. OMB No. 2070-0060. Approval expires 05-31-98 **OPP Identifier Number** Registration **United States \$EPA Environmental Protection Agency** Amendment 250768 Washington, DC 20460 Other Application for Pesticide - Section I 2. EPA Product Manager 1. Company/Product Number 3. Proposed Classification 70871-E Rebecca Cool None Restricted 4. Company/Product (Name) PM# BioShield AM 500 I 31 5. Name and Address of Applicant (Include ZIP Code) 6. Expedited Review. In accordance with FIFRA Section 3(c)(3) BioShield Technologies, Inc. (b)(i), my product is similar or identical in composition and labeling 4405 International Blvd., Suite B109 Norcross, GA 30093 EPA Reg. No. Check if this is a new address **Product Name** Section - II Amendment - Explain below. Final printed labels in response to Agency letter dated Resubmission in response to Agency letter dated "Me Too" Application. Notification - Explain below. Other - Explain below. Explanation: Use additional page(s) if necessary. (For section I and Section II.) Application for new manufacturing-use product registration Section - III 1. Material This Product Will Be Packaged In: Water Soluble Packaging 2. Type of Container Child-Resistant Packaging **Unit Packaging** Metal Yes* Yes Yes Plastic No No Glass If "Yes" Unit Packaging wgt. Paper No. per If "Yes" No. per Certification must container Package wgt container Other (Specify) be submitted 5. Location of Label Directions 3. Location of Net Contents Information 4. Size(s) Retail Container On Label 8oz., 1gal., 5gal., 55gal. X Label On Labeling accompanying product Container Other 6. Manner in Which Label is Affixed to Product Lithograph Paper glued Stenciled Section - IV 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) Title Jellinek, Schwartz & Telephone No. (Include Area Code) Name Blane Dahl Connolly, Inc., Auth. Rep. of (703)312-8531 BioShield Technologies, Inc. Date Application Certification Received I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or (Stamped) both under applicable law. 3. Title Jellinek, Schwartz & Connolly, Inc. 2. Signature Auth. Rep. of BioShield Technologies Inc. 5. Date 4. Typed Name 5/14/97 Blane Dahl 310

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

- 1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
- 2. Confidential Statement of Formula (EPA Form 8570-4);
- 3. Formulator's Exemption Statement (EPA Form 8570-27);
- 4. Five copies of draft labeling;
- 5. Three copies of any data submitted;
- 6. Authorization letter where applicable;
- 7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION 1- This section must be completed, as applicable, for all registration actions.

- 1. Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4. Product Name Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- 5. Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- 6. Expedited Review FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registration that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration of applicable amendments.

- Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types.
 Indicate the size of the individual packets and number per retail container.
- 2. Type of Retail Container Indicate type of container in which product will be marketed.
- 3. Location of Net Contents Indicate the location of the net contents information for your product.
- 4. Size(s) of Retail Container Specify the net contents of all retail containers for your product.
- 5. Location of Use Directions Indicate the location of the use directions for your product.
- 6. Manner in which label is affixed to product Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
- 6. EPA Use Only.